National Health (Listing of Pharmaceutical Benefits) Instrument 2012

PB 71 of 2012

made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the

National Health Act 1953

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This compilation is in 7 volumes

Volume 1:	sections 1–26 and Schedule 1 (Part 1: A–C)
Volume 2:	Schedule 1 (Part 1: D–K)
Volume 3:	Schedule 1 (Part 1: L–P)
Volume 4:	Schedule 1 (Part 1: Q–Z, Part 2), Schedules 2 and 3
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Volume 7:	Schedule 4 (Part 1: S–Z, Part 3), Schedule 5 and Endnotes

Each volume has its own contents

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About this compilation

This compilation

This is a compilation of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* that shows the text of the law as amended and in force on 1 March 2024 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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Part 1—Circumstances, purposes and conditions 1

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Schedule 4—Circumstances, purposes and conditions codes

(sections 10-15,17, 18, 20 and 21)

Part 1—Circumstances, purposes and conditions

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
Abacavir	C4454			HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512			HIV infection Initial Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 4512
	C13920			Human immunodeficiency virus (HIV) infection Patient must be less than 13.00 years of age. Patient must be unable to take a solid dose form of this drug; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures
Abacavir with lamivudine	C4527			HIV infection Initial Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents. Patient must be aged 12 years or older; AND Patient must weigh 40 kg or more.	Compliance with Authority Required procedures - Streamlined Authority Code 4527
	C4528			HIV infection Continuing	Compliance with Authority Required

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents. Patient must be aged 12 years or older; AND Patient must weigh 40 kg or more.	procedures - Streamlined Authority Code 4528
Abacavir with lamivudine and zidovudine	C4480			HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection. Patient must be aged 12 years or older; AND Patient must weigh 40 kg or more.	Compliance with Authority Required procedures - Streamlined Authority Code 4480
	C4495			HIV infection Initial Patient must be antiretroviral treatment naive. Patient must be aged 12 years or older; AND Patient must weigh 40 kg or more.	Compliance with Authority Required procedures - Streamlined Authority Code 4495
Abatacept	C14488	P14488		Severe active rheumatoid arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				available under the above restrictions.	
	C14507	P14507		Severe active rheumatoid arthritis First continuing treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment.	Compliance with Authority Required procedures
	C14519	P14519		Severe active rheumatoid arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14522	P14522		Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be at least 18 years of age. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats. Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with	

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				this drug for this condition.	
	C14555			Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.	Compliance with Authority Required procedures - Streamlined Authority Code 14555

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.	
	C14560	P14560		Severe active rheumatoid arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L;	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats.	

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				The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats. Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14583	P14583		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats. Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological	

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				medicine.	
	C14604	P14604		Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.	Compliance with Authority Required procedures - Streamlined Authority Code 14604

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.	
Abemaciclib	C13035			Locally advanced or metastatic breast cancer Initial treatment Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR The treatment must be in combination, where the patient has recurrence/progressive	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only; AND The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy. Patient must not be premenopausal.	
	C13036			Locally advanced or metastatic breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant; AND The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy. Patient must not be premenopausal.	Compliance with Authority Required procedures
Abiraterone	C13945			Castration resistant metastatic carcinoma of the prostate The treatment must be used in combination with a corticosteroid; AND The treatment must not be used in combination with chemotherapy; AND Patient must have a WHO performance status of 2 or less; AND The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits; AND Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
Abiraterone and methylprednisolone	C13992			Castration resistant metastatic carcinoma of the prostate The treatment must not be used in combination with chemotherapy; AND Patient must have a WHO performance status of 2 or less; AND The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits; AND Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.	Compliance with Authority Required procedures
	C14034			Metastatic castration sensitive carcinoma of the prostate The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy; AND Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug. Patient must be undergoing concurrent androgen deprivation therapy.	Compliance with Authority Required procedures
Acalabrutinib	C12495	P12495		Mantle cell lymphoma Initial treatment The condition must have relapsed or be refractory to at least one prior therapy; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must be untreated with Bruton's tyrosine kinase inhibitor therapy; OR	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication.	
	C12500	P12500		Mantle cell lymphoma Continuing treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition.	Compliance with Authority Required procedures
	C14788	P14788		Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Treatment of relapsed/refractory disease The condition must have relapsed or be refractory to at least one prior therapy; AND The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication. Patient must not be undergoing retreatment (second/subsequent treatment course) with this drug where prior treatment of CLL/SLL with this same drug was unable to prevent disease progression; AND Patient must be undergoing treatment through this treatment phase listing for the first time (initial treatment); OR Patient must be undergoing continuing treatment through this treatment phase listing, with disease progression being absent.	Compliance with Authority Required procedures
	C14795	P14795		Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) First line drug treatment of this indication - as monotherapy The condition must be untreated with acalabrutinib at the time of the first dose of this drug; OR Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				treatment of CLL/SLL; AND The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication. Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug; OR Patient must be undergoing continuing treatment with this drug - the condition has not progressed whilst the patient has actively been on this drug.	
	C14800	P14800		Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) First line drug treatment of this indication - in combination with obinutuzumab The condition must be untreated with acalabrutinib at the time of the first dose of this drug; OR Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL; AND The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND The treatment must be initiated as a monotherapy for 1 Cycle with treatment in combination with obinutuzumab from Cycle 2 to 7 (refer to Product Information for timing of obinutuzumab and acalabrutinib doses) after which treatment must be monotherapy. Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug; OR Patient must be undergoing continuing treatment with this drug - the condition has not progressed whilst the patient has actively been on this drug.	Compliance with Authority Required procedures
Acamprosate	C5366			Alcohol dependence The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence.	Compliance with Authority Required procedures - Streamlined

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					Authority Code 5366
Acarbose		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Aciclovir	C5936	P5936		Initial moderate to severe genital herpes Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.	Compliance with Authority Required procedures - Streamlined Authority Code 5936
	C5942	P5942		Recurrent moderate to severe genital herpes Episodic treatment or suppressive therapy Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.	Compliance with Authority Required procedures - Streamlined Authority Code 5942
	C5959			Herpes zoster ophthalmicus	Compliance with Authority Required procedures - Streamlined Authority Code 5959
	C5964			Herpes simplex keratitis	
	C5965			Herpes simplex keratitis	
	C5967			Herpes zoster The treatment must be administered within 72 hours of the onset of the rash.	Compliance with Authority Required procedures - Streamlined Authority Code 5967
Acitretin	C5727			Severe disorders of keratinisation	Compliance with Authority Required procedures - Streamlined Authority Code 5727

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C5789			Severe intractable psoriasis	Compliance with Authority Required procedures - Streamlined Authority Code 5789
Aclidinium	C4516			Chronic obstructive pulmonary disease (COPD)	
Aclidinium with formoterol	C7798			Chronic obstructive pulmonary disease (COPD) Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR Patient must have been stabilised on a combination of a LAMA and a LABA.	Compliance with Authority Required procedures - Streamlined Authority Code 7798
Adalimumab	C9064	P9064		Severe psoriatic arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C9386	P9386		Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	Compliance with Authority Required procedures
	C9715	P9715		Moderate to severe ulcerative colitis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	
	C11107	P11107		Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must be as systemic monotherapy (other than methotrexate); AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a dermatologist.	
	C11523	P11523		Severe psoriatic arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the	Compliance with Authority Required procedures - Streamlined Authority Code 11523

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C11524	P11524		Complex refractory Fistulising Crohn disease Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle; AND Patient must have demonstrated an adequate response to treatment with this drug for this condition. An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. The measurement of response to the prior course of therapy must be documented in the patient's medical notes.	Compliance with Authority Required procedures - Streamlined Authority Code 11524

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. A maximum of 24 weeks treatment will be authorised under this restriction.	
	C11529	P11529		Moderate to severe hidradenitis suppurativa Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated a response to treatment with this drug for this condition. Must be treated by a dermatologist. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.	Compliance with Authority Required procedures - Streamlined Authority Code 11529
	C11579	P11579		Moderate to severe ulcerative colitis Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater	Compliance with Authority Required procedures - Streamlined Authority Code 11579

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				than 1 while receiving treatment with this drug; OR Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be 6 years of age or older. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C11604	P11604		Severe active juvenile idiopathic arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.	Compliance with Authority Required procedures - Streamlined Authority Code 11604

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.	
	C11606	P11606		Severe chronic plaque psoriasis Subsequent continuing treatment, Face, hand, foot Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to their most recent course of treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.	Compliance with Authority Required procedures - Streamlined Authority Code 11606

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C11631	P11631		Severe Crohn disease Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. The measurement of response to the prior course of therapy must be documented in the patient's medical notes.	Compliance with Authority Required procedures - Streamlined Authority Code 11631

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C11635	P11635		Severe chronic plaque psoriasis Subsequent continuing treatment, Whole body Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 11635
	C11704	P11704		Severe Crohn disease First continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received this drug as their most recent course of PBS-subsidised	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				biological medicine treatment for this condition; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment	

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.	
	C11709	P11709		Severe Crohn disease Balance of supply Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks therapy	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				available under Initial 1, 2 or 3 treatment; OR The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment.	
	C11711	P11711		Severe Crohn disease Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.	
	C11713	P11713		Severe Crohn disease Balance of supply for paediatric patient Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR	Compliance with Authority Required procedures

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				Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist.	
	C11715	P11715		Severe Crohn disease Initial treatment - Initial 1 (new patient) Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate; AND	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment and which is no more than 4 weeks old at the time of application; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 6 to 17 years inclusive. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. The authority application must be made in writing and must include: (1) two completed authority prescription forms; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website (www.servicesaustralia.gov.au). An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				necessity for permanent withdrawal of treatment.	
	C11716	P11716		Severe Crohn disease Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist; AND Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 6 to 17 years inclusive. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. The authority application must be made in writing and must include: (1) two completed authority prescription forms; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The PCDAI assessment must be no more than 4 weeks old at the time of application. A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				a response to be demonstrated. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.	
	C11717	P11717		Severe Crohn disease Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI Patient must have a documented history of severe Crohn disease; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND Patient must have a total PCDAI score of 40 points or less; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 6 to 17 years inclusive. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. The authority application must be made in writing and must include: (1) a completed authority prescription form; and	Compliance with Written Authority Required procedures

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				(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The PCDAI assessment must be no more than 4 weeks old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.	
	C11718	P11718		Severe Crohn disease Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI Patient must have a documented history of severe Crohn disease; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND Patient must have a total PCDAI score of 40 points or less; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 6 to 17 years inclusive. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in	Compliance with Authority Required procedures - Streamlined Authority Code 11718

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. The PCDAI assessment must be no more than 4 weeks old at the time of application. Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.	
	C11759	P11759		Severe Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) two completed authority prescription forms; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				adalimumab may be requested under the balance of supply restriction. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C11761	P11761		Severe Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have a documented history of severe Crohn disease; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 6 to 17 years inclusive. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. The authority application must be made in writing and must include: (1) two completed authority prescription forms; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.	
	C11762	P11762		Severe Crohn disease Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must be aged 18 years or older. Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND	Compliance with Written Authority Required procedures

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				Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below. The authority application must be made in writing and must include: (1) two completed authority prescription forms; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following: (a) patient must have evidence of intestinal inflammation; (b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.	

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				Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction. All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless	

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				the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C11763	P11763		Severe Crohn disease Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have evidence of intestinal inflammation; OR Patient must be assessed clinically as being in a high faecal output state; OR Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) two completed authority prescription forms; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent	

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				course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C11767	P11767		Severe Crohn disease First continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI Patient must have a documented history of severe Crohn disease; AND Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND Patient must have a total PCDAI score of 40 points or less; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 6 to 17 years inclusive. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				phase (the latest version is located on the website specified in the Administrative Advice). The PCDAI assessment must be no more than 4 weeks old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.	
	C11852	P11852		Moderate to severe ulcerative colitis Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years. Patient must be 6 years of age or older. The authority application must be made in writing and must include: (1) two completed authority prescription forms; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes: (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				application. A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. Details of the accepted toxicities including severity can be found on the Services Australia website.	
	C11853	P11853		Moderate to severe ulcerative colitis Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years. Patient must be 6 years of age or older. Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C11854	P11854		Moderate to severe ulcerative colitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years. Patient must be 6 years of age or older.	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The authority application must be made in writing and must include: (1) two completed authority prescription forms; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes: (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C11855	P11855		Moderate to severe ulcerative colitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years. Patient must be 6 years of age or older. The authority application must be made in writing and must include: (1) two completed authority prescription forms; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes: (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(ii) the details of prior biological medicine treatment including the details of date and duration of treatment. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application. A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. Details of the accepted toxicities including severity can be found on the Services Australia website.	
	C11861	P11861		Severe psoriatic arthritis	Compliance with Written

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who has received PBS-subsidised treatment with this	Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C11865	P11865		Severe psoriatic arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C11867	P11867		Severe psoriatic arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C11903	P11903		Moderate to severe ulcerative colitis First continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years. Patient must be 6 years of age or older. Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the	

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C11906	P11906		Severe psoriatic arthritis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.	Compliance with Authority Required procedures
	C11966	P11966		Moderate to severe ulcerative colitis Continuing treatment - balance of supply Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction.	
	C12098	P12098		Complex refractory Fistulising Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Applications for authorisation must be made in writing and must include:	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(1) two completed authority prescription forms; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and (ii) details of prior biological medicine treatment including details of date and duration of treatment. The most recent fistula assessment must be no more than 4 weeks old at the time of application. A maximum of 16 weeks of treatment with this drug will be approved under this criterion.	
	C12101	P12101		Complex refractory Fistulising Crohn disease Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) - balance of supply Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	Compliance with Authority Required procedures
	C12103	P12103		Severe chronic plaque psoriasis Initial treatment - Initial 3, Whole body (recommencement of treatment after a break	Compliance with Written Authority Required

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				in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with	procedures

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				this drug for this condition within this treatment cycle.	
	C12105	P12105		Severe chronic plaque psoriasis Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the	Compliance with Written Authority Required procedures

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				continuing restriction. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C12122	P12122		Severe active juvenile idiopathic arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or	Compliance with Written Authority Required procedures

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				(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	

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				If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C12123	P12123		Severe active juvenile idiopathic arthritis Continuing treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.	Compliance with Authority Required procedures
	C12147	P12147		Complex refractory Fistulising Crohn disease Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have an externally draining enterocutaneous or rectovaginal fistula. Applications for authorisation must be made in writing and must include: (1) two completed authority prescription forms; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative	Compliance with Written Authority Required procedures

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				Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application. A maximum of 16 weeks of treatment with this drug will be approved under this criterion. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.	
	C12148	P12148		Complex refractory Fistulising Crohn disease Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug for this condition. An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. Applications for authorisation must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative	Compliance with Written Authority Required procedures

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				Advice) which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition. The most recent fistula assessment must be no more than 4 weeks old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction. A maximum of 24 weeks treatment will be authorised under this restriction.	
	C12152	P12152		Complex refractory Fistulising Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND	Compliance with Written Authority Required procedures

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				Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Applications for authorisation must be made in writing and must include: (1) two completed authority prescription forms; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and (ii) details of prior biological medicine treatment including details of date and duration of treatment. The most recent fistula assessment must be no more than 4 weeks old at the time of application. A maximum of 16 weeks of treatment with this drug will be approved under this criterion.	
	C12155	P12155		Severe chronic plaque psoriasis Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised	Compliance with Written Authority Required procedures

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				treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets	

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				including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C12156	P12156		Severe chronic plaque psoriasis Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND The treatment must be as systemic monotherapy (other than methotrexate). Must be treated by a dermatologist.	Compliance with Authority Required procedures
	C12157	P12157		Severe chronic plaque psoriasis Subsequent continuing treatment, Whole body Patient must have previously received PBS-subsidised treatment with this drug for	Compliance with Written Authority Required procedures

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				this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 4 weeks old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this	

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				restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C12158	P12158		Severe chronic plaque psoriasis First continuing treatment, Whole body Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 4 weeks old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.	Compliance with Written Authority Required procedures

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				An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C12174	P12174		Ankylosing spondylitis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR	Compliance with Authority Required procedures

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				Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	
	C12189	P12189		Severe chronic plaque psoriasis First continuing treatment, Face, hand, foot Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 4 weeks old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same	Compliance with Written Authority Required procedures

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				affected area assessed at baseline. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C12190	P12190		Severe chronic plaque psoriasis Subsequent continuing treatment, Face, hand, foot Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this	Compliance with Written Authority Required procedures

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				level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 4 weeks old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C12194	P12194		Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Advice). An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C12212	P12212		Severe chronic plaque psoriasis	Compliance with Written

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.	Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C12214	P12214		Severe active juvenile idiopathic arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless	

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				the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient doses for up to 24 weeks treatment. Up to a maximum of 5 repeats will be authorised. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.	
	C12228	P12228		Complex refractory Fistulising Crohn disease First continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug for	Compliance with Written Authority Required procedures

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				this condition. An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. Applications for authorisation must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition. The most recent fistula assessment must be no more than 4 weeks old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction. A maximum of 24 weeks treatment will be authorised under this restriction.	

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C12229	P12229		Complex refractory Fistulising Crohn disease Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have an externally draining enterocutaneous or rectovaginal fistula. Applications for authorisation must be made in writing and must include: (1) two completed authority prescription forms; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application. A maximum of 16 weeks of treatment with this drug will be approved under this criterion. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.	Compliance with Written Authority Required procedures
	C12240	P12240		Complex refractory Fistulising Crohn disease Continuing treatment - balance of supply Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.	
	C12272	P12272		Moderate to severe hidradenitis suppurativa Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated a response to treatment with this drug for this condition. Must be treated by a dermatologist. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment. The authority application must be made in writing and must include:	Compliance with Written Authority Required procedures

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				(1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.	
	C12273	P12273		Moderate to severe hidradenitis suppurativa Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (recommencement of treatment) restriction to complete 16 weeks treatment. Must be treated by a dermatologist. A maximum of 12 weeks of treatment will be authorised under this restriction.	Compliance with Authority Required procedures
	C12275	P12275		Moderate to severe hidradenitis suppurativa Initial treatment - Initial 2 (recommencement of treatment) Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition; AND The treatment must be limited to a maximum duration of 16 weeks. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes: (i) the Hurley stage grading; and (ii) the AN count.	
	C12278	P12278		Moderate to severe hidradenitis suppurativa Initial treatment - Initial 1 (new patient) Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				condition; AND The treatment must be limited to a maximum duration of 16 weeks. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes: (i) the Hurley stage grading; and (ii) the AN count; and (iii) the name of the antibiotic/s received for two separate courses each of three months; or (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.	
	C12306	P12306		Moderate to severe hidradenitis suppurativa	Compliance with Written

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated a response to treatment with this drug for this condition. Must be treated by a dermatologist. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.	Authority Required procedures
	C12315	P12315		Moderate to severe hidradenitis suppurativa First continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated a response to treatment with this drug for this condition.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a dermatologist. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.	
	C12336	P12336		Moderate to severe hidradenitis suppurativa Initial treatment - Initial 1 (new patient) Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; AND The treatment must be limited to a maximum duration of 16 weeks. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes: (i) the Hurley stage grading; and (ii) the AN count; and (iii) the name of the antibiotic/s received for two separate courses each of three months; or (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of	

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.	
	C13556	P13556		Severe chronic plaque psoriasis Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C13599	P13599		Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Active joints are defined as: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measurements must be no more than 4 weeks old at the time of this application. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C13602	P13602		Severe Crohn disease Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in	Compliance with Written Authority Required procedures

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				gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must be at least 18 years of age. Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below. The authority application must be made in writing and must include: (1) two completed authority prescription forms; and	

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following: (a) patient must have evidence of intestinal inflammation; (b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient. Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction. All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website.	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C13609	P13609		Severe Crohn disease Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND Patient must have evidence of intestinal inflammation; OR Patient must be assessed clinically as being in a high faecal output state; OR Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) two completed authority prescription forms; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C13612	P13612		Severe chronic plaque psoriasis Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be at least 18 years of age. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C13650	P13650		Severe psoriatic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				phase (the latest version is located on the website specified in the Administrative Advice). An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C13681	P13681		Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment	

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				failure.	
	C13694	P13694		Severe psoriatic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14107			Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.	Compliance with Authority Required procedures - Streamlined Authority Code 14107

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				Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved	

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				in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C14136			Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application. The assessment of the patient's response to the most recent course of biological	Compliance with Authority Required procedures - Streamlined Authority Code 14136

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C14377	P14377		Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be at least 18 years of age. Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].	

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				An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C14378	P14378		Severe chronic plaque psoriasis Initial treatment - Initial 1, Face, hand, foot (new patient) Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and	

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				(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C14398	P14398		Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks	

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				prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C14399	P14399		Severe chronic plaque psoriasis Initial treatment - Initial 1, Face, hand, foot (new patient) Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin,	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].	

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				An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C14483	P14483		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20	

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				active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	
	C14486	P14486		Severe active rheumatoid arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater	Compliance with Written Authority Required procedures

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				than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological	

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				medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14488	P14488		Severe active rheumatoid arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	Compliance with Authority Required procedures
	C14493	P14493		Severe active rheumatoid arthritis First continuing treatment	Compliance with Written Authority Required

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				Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the	procedures

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				assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14496	P14496		Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot	Compliance with Authority Required procedures

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				be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.	

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				The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to prior treatment must be documented in the patient's medical records. The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records: (a) the active joint count, ESR and/or CRP result and date of results; (b) details of prior treatment, including dose and date/duration of treatment. (c) If applicable, details of any contraindications/intolerances. (d) If applicable, the maximum tolerated dose of methotrexate.	

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				An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14498	P14498		Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR	Compliance with Written Authority Required procedures

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				Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or	

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				(b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with	

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				this drug for this condition.	
	C14499	P14499		Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total	Compliance with Authority Required procedures - Streamlined Authority Code 14499

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				number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14507	P14507		Severe active rheumatoid arthritis First continuing treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment.	Compliance with Authority Required procedures
	C14567	P14567		Severe active rheumatoid arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L	Compliance with Authority Required procedures - Streamlined Authority Code 14567

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				or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14568	P14568		Severe active rheumatoid arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological	Compliance with Authority Required procedures

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				medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.	

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				The following information must be provided by the prescriber at the time of application and documented in the patient's medical records: (a) the active joint count, ESR and/or CRP result and date of result; (b) the most recent biological agent and the date of the last continuing prescription. (c) If applicable, the new baseline scores. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14590	P14590		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND	Compliance with Authority Required procedures

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				Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological	

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				medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	
	C14655	P14655		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of	Compliance with Written Authority Required procedures

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				ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient	

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				will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14656	P14656		Ankylosing spondylitis Subsequent continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or	Compliance with Written Authority Required procedures

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				(b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14662	P14662		Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND	Compliance with Written Authority Required procedures

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				Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level.	

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				To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14670	P14670		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the	

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14672	P14672		Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the	

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				necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14673	P14673		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14683	P14683		Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:	Compliance with Authority Required procedures - Streamlined Authority Code 14683

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				(a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14701	P14701		Ankylosing spondylitis Subsequent continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	Compliance with Authority Required procedures - Streamlined Authority Code 14701

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14713	P14713		Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include:	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14730	P14730		Ankylosing spondylitis Continuing treatment - balance of supply	Compliance with Authority Required

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	procedures
Adapalene with benzoyl peroxide	C4898	P4898		Severe acne vulgaris The treatment must be maintenance therapy.	
	C4961	P4961		Severe acne vulgaris Acute treatment The treatment must in combination with an oral antibiotic.	
	C14275	P14275		Severe acne vulgaris The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be maintenance therapy.	
Adefovir	C4490			Chronic hepatitis B infection Patient must not have cirrhosis; AND Patient must have failed antihepadnaviral therapy; AND Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.	Compliance with Authority Required procedures - Streamlined Authority Code 4490

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C4510			Chronic hepatitis B infection Patient must have cirrhosis; AND Patient must have failed antihepadnaviral therapy; AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 4510
Adrenaline (epinephrine)	C4909			Acute allergic reaction with anaphylaxis Initial sole PBS-subsidised supply for anticipated emergency treatment Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician. The name of the specialist consulted must be provided at the time of application for initial supply.	Compliance with Authority Required procedures
	C4947			Acute allergic reaction with anaphylaxis Continuing sole PBS-subsidised supply for anticipated emergency treatment Patient must have previously been issued with an authority prescription for this drug.	Compliance with Authority Required procedures
	C8734			Acute allergic reaction with anaphylaxis Initial sole PBS-subsidised supply for anticipated emergency treatment Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.	Compliance with Authority Required procedures
Afatinib	C4473			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)	Compliance with Authority Required

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Initial treatment The treatment must be as monotherapy; AND The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal; AND Patient must have a WHO performance status of 2 or less. Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.	procedures
	C7613			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be as monotherapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition. Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.	Compliance with Authority Required procedures - Streamlined Authority Code 7613
Aflibercept	C13336	P13336		Central retinal vein occlusion with macular oedema Continuing treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 13336

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C13337	P13337		Subfoveal choroidal neovascularisation (CNV) Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. The condition must be due to pathologic myopia (PM); AND The condition must be diagnosed by optical coherence tomography; OR The condition must be diagnosed by fluorescein angiography; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. If the application is submitted through HPOS form upload or mail, it must include: (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.	Compliance with Written Authority Required procedures
	C13384	P13384		Branch retinal vein occlusion with macular oedema Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO); AND Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment; AND The condition must be diagnosed by optical coherence tomography; OR The condition must be diagnosed by fluorescein angiography; AND	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. If the application is submitted through HPOS form upload or mail, it must include: (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.	
	C13387	P13387		Branch retinal vein occlusion with macular oedema Continuing treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 13387
	C13388	P13388		Diabetic macular oedema (DMO) Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Patient must have visual impairment due to diabetic macular oedema; AND Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment; AND The condition must be diagnosed by optical coherence tomography; OR The condition must be diagnosed by fluorescein angiography; AND	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must be as monotherapy; OR The treatment must be in combination with laser photocoagulation; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. If the application is submitted through HPOS form upload or mail, it must include: (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.	
	C13390	P13390		Central retinal vein occlusion with macular oedema Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO); AND Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment; AND The condition must be diagnosed by optical coherence tomography; OR The condition must be diagnosed by fluorescein angiography; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. If the application is submitted through HPOS form upload or mail, it must include: (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.	
	C13392	P13392		Subfoveal choroidal neovascularisation (CNV) Continuing treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. The condition must be due to pathologic myopia (PM); AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.	Compliance with Authority Required procedures - Streamlined Authority Code 13392
	C13402	P13402		Diabetic macular oedema (DMO) Continuing treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND The treatment must be as monotherapy; OR The treatment must be in combination with laser photocoagulation; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 13402
	C13406	P13406		Subfoveal choroidal neovascularisation (CNV) Continuing treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. The condition must be due to age-related macular degeneration (AMD); AND The treatment must be the sole PBS-subsidised therapy for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority Code 13406

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.	
	C13424	P13424		Subfoveal choroidal neovascularisation (CNV) Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. The condition must be due to age-related macular degeneration (AMD); AND The condition must be diagnosed by optical coherence tomography; OR The condition must be diagnosed by fluorescein angiography; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. If the application is submitted through HPOS form upload or mail, it must include: (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.	Compliance with Written Authority Required procedures
Albendazole	C5607			Hydatid disease The treatment must be in conjunction with surgery; OR The treatment must be used when a surgical cure cannot be achieved; OR The treatment must be used when surgery cannot be used.	Compliance with Authority Required procedures - Streamlined Authority Code 5607
	C5680	P5680		Tapeworm infestation	Compliance with Authority Required procedures - Streamlined Authority Code 5680

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C5712	P5712		Strongyloidiasis	Compliance with Authority Required procedures - Streamlined Authority Code 5712
	C5797	P5797		Hookworm infestation	Compliance with Authority Required procedures - Streamlined Authority Code 5797
	C5817	P5817		Whipworm infestation Patient must be an Aboriginal or a Torres Strait Islander person.	Compliance with Authority Required procedures - Streamlined Authority Code 5817
Alectinib	C7345			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment The treatment must be as monotherapy; AND The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND Patient must have a WHO performance status of 2 or less. Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.	Compliance with Authority Required procedures
	C7346			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be as monotherapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop disease progression while receiving PBS-subsidised	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				treatment with this drug for this condition.	
Alemtuzumab	C6847	P6847		Multiple sclerosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not show continuing progression of disability while on treatment with this drug; AND Patient must not receive more than one PBS-subsidised treatment per year; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy. Must be treated by a neurologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6847
	C7714	P7714		Multiple sclerosis Initial treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support). Must be treated by a neurologist. Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 7714

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C9589	P9589		Multiple sclerosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not show continuing progression of disability while on treatment with this drug; AND Patient must not receive more than one PBS-subsidised treatment per year; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy. Must be treated by a neurologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9589
	C9636	P9636		Multiple sclerosis Initial treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support). Must be treated by a neurologist. Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 9636
Alendronic acid	C6310	P6310		Osteoporosis Patient must be aged 70 years or older.	

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				Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.	
	C6323	P6323		Corticosteroid-induced osteoporosis Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy; AND Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.	
	C6327	P6327		Established osteoporosis Patient must have fracture due to minimal trauma; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.	
	C14242	P14242		Osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must be aged 70 years or older. Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less; AND	

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				Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.	
	C14291	P14291		Established osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have fracture due to minimal trauma; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.	
	C14309	P14309		Corticosteroid-induced osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy; AND Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.	
Alendronic acid	C6306	P6306		Corticosteroid-induced osteoporosis Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg	Compliance with Authority Required

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with colecalciferol				per day prednisolone or equivalent) corticosteroid therapy; AND Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.	procedures - Streamlined Authority Code 6306
	C6307	P6307		Corticosteroid-induced osteoporosis Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy; AND Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 6307
	C6315	P6315		Established osteoporosis Patient must have fracture due to minimal trauma; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.	Compliance with Authority Required procedures - Streamlined Authority Code 6315
	C6319	P6319		Established osteoporosis Patient must have fracture due to minimal trauma; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.	Compliance with Authority Required procedures - Streamlined

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				The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.	Authority Code 6319
	C6320	P6320		Osteoporosis Patient must be aged 70 years or older. Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 6320
	C6325	P6325		Osteoporosis Patient must be aged 70 years or older. Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 6325
	C14898	P14898		Osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must be aged 70 years or older. Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD	Compliance with Authority Required procedures - Streamlined Authority Code 14898

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				measurement must be documented in the patient's medical records when treatment is initiated.	
	C14993	P14993		Established osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have fracture due to minimal trauma; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.	Compliance with Authority Required procedures - Streamlined Authority Code 14993
	C15011	P15011		Osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must be aged 70 years or older. Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 15011
	C15024	P15024		Corticosteroid-induced osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy; AND Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less; AND	Compliance with Authority Required procedures - Streamlined Authority Code 15024

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				Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.	
	C15032	P15032		Corticosteroid-induced osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy; AND Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 15032
	C15035	P15035		Established osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have fracture due to minimal trauma; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.	Compliance with Authority Required procedures - Streamlined Authority Code 15035
Alirocumab	C12008			Familial heterozygous hypercholesterolaemia Initial treatment	Compliance with Authority Required

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				The treatment must be in conjunction with dietary therapy and exercise; AND The condition must have been confirmed by genetic testing; OR The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6; AND Patient must have an LDL cholesterol level in excess of 2.6 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; OR Patient must have an LDL cholesterol level in excess of 5 millimoles per litre; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; AND Patient must not be receiving concomitant PBS-subsidised treatment with another drug that belongs to the same pharmacological class as this drug, for this PBS indication. Must be treated by a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic	procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal. In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved. The following must be stated at the time of application and documented in the patient's medical records: (i) the qualifying Dutch Lipid Clinic Network Score; or (ii) the result of genetic testing confirming a diagnosis of familial heterozygous	

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				hypercholesterolaemia One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.	
	C12010			Non-familial hypercholesterolaemia Continuing treatment with this drug or switching treatment from another drug within the same pharmacological class Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR Patient must have received PBS-subsidised treatment with a drug from the same pharmacological class as this drug for this PBS indication; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must not be receiving concomitant PBS-subsidised treatment with another drug that belongs to the same pharmacological class as this drug.	Compliance with Authority Required procedures - Streamlined Authority Code 12010
	C12011			Familial heterozygous hypercholesterolaemia Continuing treatment with this drug or switching treatment from another drug within the same pharmacological class Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR Patient must have received PBS-subsidised treatment with a drug from the same pharmacological class as this drug for this PBS indication; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must not be receiving concomitant PBS-subsidised treatment with another drug that belongs to the same pharmacological class as this drug, for this PBS indication.	Compliance with Authority Required procedures - Streamlined Authority Code 12011

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	C12054			Non-familial hypercholesterolaemia Initial treatment The treatment must be in conjunction with dietary therapy and exercise; AND Patient must not be receiving concomitant PBS-subsidised treatment with another drug that belongs to the same pharmacological class as this drug; AND Patient must have symptomatic atherosclerotic cardiovascular disease; AND Patient must have an LDL cholesterol level in excess of 2.6 millimoles per litre prior to commencing treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9); AND Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); OR Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; OR Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in	Compliance with Authority Required procedures

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				conjunction with a statin (if tolerated), dietary therapy and exercise. Must be treated by a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal. In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved. One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event: (i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or (ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or (iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or (iv) diabetes mellitus with microalbuminuria; or (v) diabetes mellitus and age 60 years of more; or (vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or (vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher	
Allopurinol		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
Alogliptin	C4349	P4349		Diabetes mellitus type 2 The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with alogliptin.	Compliance with Authority Required procedures - Streamlined Authority Code 4349
	C14862	P14862		Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% despite	Compliance with Authority Required procedures - Streamlined Authority Code 14862

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with alogliptin.	
Alogliptin with metformin	C4423	P4423		Diabetes mellitus type 2 Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 4423

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.	
	C4427	P4427		Diabetes mellitus type 2 Continuing Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and alogliptin.	Compliance with Authority Required procedures - Streamlined Authority Code 4427
	C14876	P14876		Diabetes mellitus type 2 Continuing The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and alogliptin.	Compliance with Authority Required procedures - Streamlined Authority Code 14876
Alprazolam	C6773			Panic disorder The treatment must be for use when other treatments have failed; OR The treatment must be for use when other treatments are inappropriate.	Compliance with Authority Required procedures
Amantadine	C5132			Parkinson disease The condition must not be drug induced.	

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Amifampridine	C12979			Lambert-Eaton myasthenic syndrome (LEMS) The condition must not be any of: (i) myasthenia gravis, (ii) Guillain-Barre syndrome. Must be treated by a prescriber type identifying as at least one of the following: (i) a clinical immunologist, (ii) a neurologist, (iii) a medical practitioner working under the direct supervision of one of these mentioned specialists.	Compliance with Authority Required procedures
Amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids	C4305	P4305		Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. The condition must not be isolated infant colic or reflux. Patient must be older than 24 months of age. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4312	P4312		Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides). Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4323	P4323		Cows' milk protein enteropathy Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must not be isolated infant colic or reflux; AND Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	
	C4330	P4330		Cows' milk anaphylaxis Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist. Patient must be up to the age of 24 months. Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4337	P4337		Cows' milk protein enteropathy Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists. The condition must not be isolated infant colic or reflux; AND Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4338	P4338		Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Continuing treatment	Compliance with Authority Required

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months. The condition must not be isolated infant colic or reflux. Patient must be older than 24 months of age. The name of the specialist and the date of birth of the patient must be included in the authority application.	procedures
	C4339	P4339		Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4345	P4345		Severe cows' milk protein enteropathy with failure to thrive Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists. The condition must not be isolated infant colic or reflux; AND Patient must have had failure to thrive prior to commencement with initial treatment. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4352	P4352		Severe cows' milk protein enteropathy with failure to thrive Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must not be isolated infant colic or reflux. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	
	C4368	P4368		Eosinophilic oesophagitis Initial treatment for up to 3 months Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist. Patient must require an amino acid based formula as a component of a dietary elimination program. Patient must be 18 years of age or less. Treatment with oral steroids should not be commenced during the period of initial treatment. Eosinophilic oesophagitis is demonstrated by the following criteria: (i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and (ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and (iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4414	P4414		Eosinophilic oesophagitis Continuing treatment Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist. Patient must have responded to an initial course of PBS-subsidised treatment. Patient must be 18 years of age or less. Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.	
	C4415	P4415		Severe intestinal malabsorption including short bowel syndrome Patient must have failed to respond to protein hydrolysate formulae; OR Patient must have been receiving parenteral nutrition.	Compliance with Authority Required procedures
Amino acid formula with carbohydrate, vitamins, minerals and trace elements without phenylalanine	C4295			Phenylketonuria	
Amino acid formula with carbohydrate without phenylalanine	C4295			Phenylketonuria	
Amino acid formula with fat, carbohydrate, vitamins, minerals, and trace elements, without methionine and supplemented with docosahexanoic acid	C5534			Pyridoxine non-responsive homocystinuria	
Amino acid formula with fat, carbohydrate,	C5970			Phenylketonuria	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
vitamins, minerals and trace elements without phenylalanine					
Amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine	C5533			Tyrosinaemia	
Amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexanoic acid	C5533			Tyrosinaemia	
Amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides	C4305			Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. The condition must not be isolated infant colic or reflux. Patient must be older than 24 months of age. The name of the specialist and the date of birth of the patient must be included in the	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				authority application.	
	C4312			Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides). Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4323			Cows' milk protein enteropathy Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. The condition must not be isolated infant colic or reflux; AND Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4330			Cows' milk anaphylaxis Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist. Patient must be up to the age of 24 months. Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction. The name of the specialist and the date of birth of the patient must be included in the	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				authority application.	
	C4337			Cows' milk protein enteropathy Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists. The condition must not be isolated infant colic or reflux; AND Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4338			Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months. The condition must not be isolated infant colic or reflux. Patient must be older than 24 months of age. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4339			Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment. Patient must be up to the age of 24 months.	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The name of the specialist and the date of birth of the patient must be included in the authority application.	
	C4345			Severe cows' milk protein enteropathy with failure to thrive Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists. The condition must not be isolated infant colic or reflux; AND Patient must have had failure to thrive prior to commencement with initial treatment. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4352			Severe cows' milk protein enteropathy with failure to thrive Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. The condition must not be isolated infant colic or reflux. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4415			Severe intestinal malabsorption including short bowel syndrome Patient must have failed to respond to protein hydrolysate formulae; OR Patient must have been receiving parenteral nutrition.	Compliance with Authority Required procedures
	C5945			Eosinophilic oesophagitis Initial treatment for up to 3 months Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist. Patient must require an amino acid based formula as a component of a dietary elimination program.	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be 18 years of age or less. Treatment with oral steroids should not be commenced during the period of initial treatment. Eosinophilic oesophagitis is demonstrated by the following criteria: (i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and (ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and (iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The date of birth of the patient must be included in the authority application.	
	C5974			Eosinophilic oesophagitis Continuing treatment Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist. Patient must have responded to an initial course of PBS-subsidised treatment. Patient must be 18 years of age or less. Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.	Compliance with Authority Required procedures
Amino acid formula with fat, carbohydrate without methionine	C5534			Pyridoxine non-responsive homocystinuria	
Amino acid formula with fat, carbohydrate	C5970			Phenylketonuria	

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without phenylalanine					
Amino acid formula with fat, carbohydrate without phenylalanine and tyrosine	C5533			Tyrosinaemia	
Amino acid formula with fat, carbohydrate without valine, leucine and isoleucine	C5571			Maple syrup urine disease	
Amino acid formula without phenylalanine	C4295			Phenylketonuria	
Amino acid formula without valine, leucine and isoleucine	C5571			Maple syrup urine disease	
Amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid	C4295			Phenylketonuria	

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Amino acid formula with vitamins and minerals without lysine and low in tryptophan	C5323			Proven glutaric aciduria type 1	
	C6007			Proven glutaric aciduria type 1	
	C11482			Pyridoxine dependent epilepsy Patient must be managed on a low lysine diet for pyridoxine dependent epilepsy; AND The condition must be treated by or in consultation with a metabolic physician.	
Amino acid formula with vitamins and minerals without methionine	C5534			Pyridoxine non-responsive homocystinuria	
	C5559			Pyridoxine non-responsive homocystinuria Patient must be an infant or a very young child.	
	C6038			Pyridoxine non-responsive homocystinuria	
Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine	C5542			Propionic acidaemia	
	C5560			Methylmalonic acidaemia	
	C5986			Propionic acidaemia	
	C6055			Methylmalonic acidaemia	
Amino acid formula with vitamins and minerals without phenylalanine	C4295			Phenylketonuria	
	C4964			Phenylketonuria	
Amino acid formula with vitamins and minerals without phenylalanine and tyrosine	C4923			Tyrosinaemia	
	C5533			Tyrosinaemia	

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Amino acid formula with vitamins and minerals without valine, leucine and isoleucine	C4954			Maple syrup urine disease	
	C5571			Maple syrup urine disease	
Amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexanoic acid	C5571			Maple syrup urine disease	
Amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine	C4295			Phenylketonuria	
Amino acids-synthetic, formula	C4305	P4305		Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. The condition must not be isolated infant colic or reflux. Patient must be older than 24 months of age. The name of the specialist and the date of birth of the patient must be included in the	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				authority application.	
	C4312	P4312		Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides). Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4323	P4323		Cows' milk protein enteropathy Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. The condition must not be isolated infant colic or reflux; AND Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4330	P4330		Cows' milk anaphylaxis Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist. Patient must be up to the age of 24 months. Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction. The name of the specialist and the date of birth of the patient must be included in the	Compliance with Authority Required procedures

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				authority application.	
	C4337	P4337		Cows' milk protein enteropathy Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists. The condition must not be isolated infant colic or reflux; AND Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4338	P4338		Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months. The condition must not be isolated infant colic or reflux. Patient must be older than 24 months of age. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4339	P4339		Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment. Patient must be up to the age of 24 months.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The name of the specialist and the date of birth of the patient must be included in the authority application.	
	C4345	P4345		Severe cows' milk protein enteropathy with failure to thrive Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists. The condition must not be isolated infant colic or reflux; AND Patient must have had failure to thrive prior to commencement with initial treatment. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4352	P4352		Severe cows' milk protein enteropathy with failure to thrive Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. The condition must not be isolated infant colic or reflux. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4368	P4368		Eosinophilic oesophagitis Initial treatment for up to 3 months Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist. Patient must require an amino acid based formula as a component of a dietary elimination program. Patient must be 18 years of age or less. Treatment with oral steroids should not be commenced during the period of initial treatment. Eosinophilic oesophagitis is demonstrated by the following criteria:	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and (ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and (iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The date of birth of the patient must be included in the authority application.	
	C4414	P4414		Eosinophilic oesophagitis Continuing treatment Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist. Patient must have responded to an initial course of PBS-subsidised treatment. Patient must be 18 years of age or less. Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.	Compliance with Authority Required procedures
	C4415	P4415		Severe intestinal malabsorption including short bowel syndrome Patient must have failed to respond to protein hydrolysate formulae; OR Patient must have been receiving parenteral nutrition.	Compliance with Authority Required procedures
Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids	C4305			Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. The condition must not be isolated infant colic or reflux. Patient must be older than 24 months of age. The name of the specialist and the date of birth of the patient must be included in the	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				authority application.	
	C4312			Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides). Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4323			Cows' milk protein enteropathy Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. The condition must not be isolated infant colic or reflux; AND Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4330			Cows' milk anaphylaxis Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist. Patient must be up to the age of 24 months. Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction. The name of the specialist and the date of birth of the patient must be included in the	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				authority application.	
	C4337			Cows' milk protein enteropathy Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists. The condition must not be isolated infant colic or reflux; AND Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4338			Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months. The condition must not be isolated infant colic or reflux. Patient must be older than 24 months of age. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4339			Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment. Patient must be up to the age of 24 months.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The name of the specialist and the date of birth of the patient must be included in the authority application.	
	C4345			Severe cows' milk protein enteropathy with failure to thrive Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists. The condition must not be isolated infant colic or reflux; AND Patient must have had failure to thrive prior to commencement with initial treatment. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4352			Severe cows' milk protein enteropathy with failure to thrive Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. The condition must not be isolated infant colic or reflux. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4415			Severe intestinal malabsorption including short bowel syndrome Patient must have failed to respond to protein hydrolysate formulae; OR Patient must have been receiving parenteral nutrition.	Compliance with Authority Required procedures
Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and	C4305	P4305		Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. The condition must not be isolated infant colic or reflux.	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
medium chain triglycerides				Patient must be older than 24 months of age. The name of the specialist and the date of birth of the patient must be included in the authority application.	
	C4312	P4312		Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides). Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4323	P4323		Cows' milk protein enteropathy Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. The condition must not be isolated infant colic or reflux; AND Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4330	P4330		Cows' milk anaphylaxis Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist. Patient must be up to the age of 24 months.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction. The name of the specialist and the date of birth of the patient must be included in the authority application.	
	C4337	P4337		Cows' milk protein enteropathy Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists. The condition must not be isolated infant colic or reflux; AND Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4338	P4338		Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months. The condition must not be isolated infant colic or reflux. Patient must be older than 24 months of age. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4339	P4339		Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. Patient must have failed a trial of protein hydrolysate formulae (with or without	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				medium chain triglycerides) prior to commencement with initial treatment. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	
	C4345	P4345		Severe cows' milk protein enteropathy with failure to thrive Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists. The condition must not be isolated infant colic or reflux; AND Patient must have had failure to thrive prior to commencement with initial treatment. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4352	P4352		Severe cows' milk protein enteropathy with failure to thrive Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. The condition must not be isolated infant colic or reflux. Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application.	Compliance with Authority Required procedures
	C4368	P4368		Eosinophilic oesophagitis Initial treatment for up to 3 months Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist. Patient must require an amino acid based formula as a component of a dietary elimination program. Patient must be 18 years of age or less. Treatment with oral steroids should not be commenced during the period of initial	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				treatment. Eosinophilic oesophagitis is demonstrated by the following criteria: (i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and (ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and (iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The date of birth of the patient must be included in the authority application.	
	C4414	P4414		Eosinophilic oesophagitis Continuing treatment Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist. Patient must have responded to an initial course of PBS-subsidised treatment. Patient must be 18 years of age or less. Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.	Compliance with Authority Required procedures
	C4415	P4415		Severe intestinal malabsorption including short bowel syndrome Patient must have failed to respond to protein hydrolysate formulae; OR Patient must have been receiving parenteral nutrition.	Compliance with Authority Required procedures
	C5945			Eosinophilic oesophagitis Initial treatment for up to 3 months Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist. Patient must require an amino acid based formula as a component of a dietary elimination program.	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be 18 years of age or less. Treatment with oral steroids should not be commenced during the period of initial treatment. Eosinophilic oesophagitis is demonstrated by the following criteria: (i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and (ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and (iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The date of birth of the patient must be included in the authority application.	
	C5974			Eosinophilic oesophagitis Continuing treatment Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist. Patient must have responded to an initial course of PBS-subsidised treatment. Patient must be 18 years of age or less. Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.	Compliance with Authority Required procedures
Amiodarone	C5665			Severe cardiac arrhythmias	
Amisulpride	C4246			Schizophrenia	Compliance with Authority Required procedures - Streamlined Authority Code 4246

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Amlodipine		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Amlodipine with atorvastatin		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Amlodipine with valsartan	C4373	P4373		Hypertension The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an angiotensin II antagonist; OR The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.	
	C14257	P14257		Hypertension The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an angiotensin II antagonist; OR The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.	
Amlodipine with valsartan and hydrochlorothiazide	C4311	P4311		Hypertension The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.	
	C14272	P14272		Hypertension The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
Amoxicillin	C5843			Chronic bronchitis Patient must have acute exacerbations of the condition.	
		P5863	CN5863	Infection suspected or proven to be due to a susceptible organism The treatment must be for patients who require a liquid formulation and in whom the syrup formulations are unsuitable.	Compliance with Authority Required procedures
		P10402	CN10402	Infection Patient must be a male with acute cystitis; OR Patient must have pyelonephritis; OR Patient must have a tooth avulsion; OR Patient must have salmonella enteritis; OR Patient must have community acquired pneumonia; OR Patient must have a condition requiring prolonged oral antibiotic therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 10402
		P10404	CN10404	Infection Patient must have a condition requiring prolonged oral antibiotic therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 10404
	C10416			Community acquired pneumonia Patient must have community acquired pneumonia.	Compliance with Authority Required procedures - Streamlined Authority Code 10416
Amoxicillin with clavulanic acid	C5832	P5832		Infections where resistance to amoxicillin is proven	
	C5833			Infection where resistance to amoxicillin is suspected	
	C5893	P5893		Infection where resistance to amoxicillin is suspected	
	C5894			Infections where resistance to amoxicillin is proven	
	C10405	P10405		Infection Patient must be a male with acute cystitis; OR	Compliance with Authority Required

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have a condition requiring prolonged oral antibiotic therapy.	procedures - Streamlined Authority Code 10405
	C10413	P10413		Infection Patient must have periorbital (preseptal) cellulitis; OR Patient must have postpartum endometritis; OR Patient must have an exacerbation of bronchiectasis; OR Patient must have pyelonephritis; OR Patient must have pneumonia acquired in hospital or aged care; OR Patient must have a diabetic foot infection; OR Patient must have a condition requiring prolonged oral antibiotic therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 10413
Amylopectin, modified long chain	C5561			Glycogen storage disease	
Anakinra	C5450			Moderate to severe cryopyrin associated periodic syndromes (CAPS) Must be treated by a rheumatologist or in consultation with a rheumatologist; OR Must be treated by a clinical immunologist or in consultation with a clinical immunologist. A diagnosis of CAPS must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 5450
Anastrozole	C5464	P5464		Breast cancer The condition must be hormone receptor positive.	
	C14943	P14943		Breast cancer The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be hormone receptor positive.	
Apalutamide	C12895			Castration resistant non-metastatic carcinoma of the prostate The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition; AND The condition must be associated with a prostate-specific antigen level that was	Compliance with Authority Required procedures

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				observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation. Patient must be undergoing concurrent treatment with androgen deprivation therapy. Prescribing instructions: Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application. The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.	
	C14034			Metastatic castration sensitive carcinoma of the prostate The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy; AND Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation; AND Patient must not receive PBS-subsidised treatment with this drug if progressive	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				disease develops while on this drug. Patient must be undergoing concurrent androgen deprivation therapy.	
Apixaban	C4098	P4098		Deep vein thrombosis Initial treatment Patient must have confirmed acute symptomatic deep vein thrombosis; AND Patient must not have symptomatic pulmonary embolism.	Compliance with Authority Required procedures - Streamlined Authority Code 4098
	C4099	P4099		Deep vein thrombosis Continuing treatment Patient must have confirmed acute symptomatic deep vein thrombosis; AND Patient must not have symptomatic pulmonary embolism.	Compliance with Authority Required procedures - Streamlined Authority Code 4099
	C4132	P4132		Prevention of recurrent venous thromboembolism Continuing treatment Patient must have a history of venous thromboembolism.	Compliance with Authority Required procedures - Streamlined Authority Code 4132
	C4269	P4269		Prevention of stroke or systemic embolism Patient must have non-valvular atrial fibrillation; AND Patient must have one or more risk factors for developing stroke or systemic embolism. Risk factors for developing stroke or systemic ischaemic embolism are: (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism; (ii) age 75 years or older; (iii) hypertension; (iv) diabetes mellitus; (v) heart failure and/or left ventricular ejection fraction 35% or less.	Compliance with Authority Required procedures - Streamlined Authority Code 4269
	C4359	P4359		Prevention of venous thromboembolism Patient must be undergoing total hip replacement. Patient must require up to 10 days supply to complete a course of treatment.	Compliance with Authority Required procedures - Streamlined Authority Code 4359

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C4381	P4381		Prevention of venous thromboembolism Patient must be undergoing total knee replacement. Patient must require up to 10 days of therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 4381
	C4382	P4382		Prevention of venous thromboembolism Patient must be undergoing total knee replacement. Patient must require up to 15 days of therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 4382
	C4402	P4402		Prevention of venous thromboembolism Patient must be undergoing total hip replacement. Patient must require up to 30 days supply to complete a course of treatment.	Compliance with Authority Required procedures - Streamlined Authority Code 4402
	C4409	P4409		Prevention of venous thromboembolism Patient must be undergoing total hip replacement. Patient must require up to 15 days supply to complete a course of treatment.	Compliance with Authority Required procedures - Streamlined Authority Code 4409
	C5083	P5083		Pulmonary embolism Continuing treatment Patient must have confirmed acute symptomatic pulmonary embolism.	Compliance with Authority Required procedures - Streamlined Authority Code 5083

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C5098	P5098		Pulmonary embolism Initial treatment Patient must have confirmed acute symptomatic pulmonary embolism.	Compliance with Authority Required procedures - Streamlined Authority Code 5098
	C14264	P14264		Deep vein thrombosis Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have confirmed acute symptomatic deep vein thrombosis; AND Patient must not have symptomatic pulmonary embolism.	Compliance with Authority Required procedures - Streamlined Authority Code 14264
	C14300	P14300		Prevention of recurrent venous thromboembolism Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have a history of venous thromboembolism.	Compliance with Authority Required procedures - Streamlined Authority Code 14300
	C14302	P14302		Pulmonary embolism Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have confirmed acute symptomatic pulmonary embolism.	Compliance with Authority Required procedures - Streamlined Authority Code 14302
	C14308	P14308		Prevention of stroke or systemic embolism The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND	Compliance with Authority Required procedures - Streamlined

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have non-valvular atrial fibrillation; AND Patient must have one or more risk factors for developing stroke or systemic embolism. Risk factors for developing stroke or systemic ischaemic embolism are: (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism; (ii) age 75 years or older; (iii) hypertension; (iv) diabetes mellitus; (v) heart failure and/or left ventricular ejection fraction 35% or less.	Authority Code 14308
Apomorphine	C10830			Parkinson disease Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND The treatment must be commenced in a specialist unit in a hospital setting.	Compliance with Authority Required procedures - Streamlined Authority Code 10830
	C10844			Parkinson disease Maintenance therapy Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND Patient must have been commenced on treatment in a specialist unit in a hospital setting.	Compliance with Authority Required procedures - Streamlined Authority Code 10844
	C10863			Parkinson disease Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND The treatment must be commenced in a specialist unit in a hospital setting.	Compliance with Authority Required procedures - Streamlined Authority Code 10863
	C11385			Parkinson disease Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND The treatment must be commenced in a specialist unit in a hospital setting.	Compliance with Authority Required procedures - Streamlined Authority Code 11385
	C11445			Parkinson disease	Compliance with

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND The treatment must be commenced in a specialist unit in a hospital setting.	Authority Required procedures - Streamlined Authority Code 11445
Apremilast	C14417			Severe chronic plaque psoriasis Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; OR Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; OR Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; AND The condition must have caused significant interference with quality of life; AND Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin, (iii) deucravacitinib. Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist; OR Must be treated by a general practitioner who has been directed to continue treatment (not initiate treatment) by one of the above practitioner types. Patient must be at least 18 years of age.	Compliance with Authority Required procedures - Streamlined Authority Code 14417
Aprepitant	C4211			Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin. No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.	Compliance with Authority Required procedures - Streamlined Authority Code 4211

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	C4215			Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer; AND The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline. No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.	Compliance with Authority Required procedures - Streamlined Authority Code 4215
	C4216			Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer; AND The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline. No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.	Compliance with Authority Required procedures - Streamlined Authority Code 4216
	C4223			Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin. No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.	Compliance with Authority Required procedures - Streamlined Authority Code 4223

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	C6370			Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle; AND Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin. No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.	Compliance with Authority Required procedures - Streamlined Authority Code 6370
	C6383			Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle; AND Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin. No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.	Compliance with Authority Required procedures - Streamlined Authority Code 6383
	C6444			Nausea and vomiting The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy; AND The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle; AND Patient must have had a prior episode of chemotherapy induced nausea or vomiting; AND Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine;	Compliance with Authority Required procedures - Streamlined Authority Code 6444

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed. No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.	
	C6464			Nausea and vomiting The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy; AND The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle; AND Patient must have had a prior episode of chemotherapy induced nausea or vomiting; AND Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed. No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.	Compliance with Authority Required procedures - Streamlined Authority Code 6464
Arachidonic acid and docosahexaenoic acid with carbohydrate	C6141			Peroxisomal biogenesis disorders	

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Arginine with carbohydrate	C4555			Urea cycle disorders	
Aripiprazole	C4246			Schizophrenia	Compliance with Authority Required procedures - Streamlined Authority Code 4246
Armodafinil	C10935			Narcolepsy Initial 2 - treatment of narcolepsy with cataplexy Must be treated by a qualified sleep medicine practitioner or neurologist. The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal; AND Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months; AND Patient must have a definite history of cataplexy documented in their medical records for auditing purposes; AND Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia. The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk: (a) a psychiatric disorder; (b) a cardiovascular disorder; (c) a history of substance abuse; (d) glaucoma; (e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.	Compliance with Authority Required procedures
	C10967			Narcolepsy Continuing or change of treatment Patient must have previously received PBS-subsidised treatment with this drug for	Compliance with Authority Required procedures

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				this condition; OR Patient must have previously received PBS-subsidised treatment with modafinil for this condition.	
	C10970			Narcolepsy Initial 1 - treatment of narcolepsy without cataplexy Must be treated by a qualified sleep medicine practitioner or neurologist. The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal; AND Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months; AND Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep; AND Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia. The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk: (a) a psychiatric disorder; (b) a cardiovascular disorder; (c) a history of substance abuse; (d) glaucoma; (e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information. The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration. The authority application must be made in writing and must include the following: (a) a completed authority prescription form; and (b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(c) details of the contraindication or intolerance to dexamfetamine sulfate; and (d) either: (i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or (ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist. The polysomnography, MSLT or EEG test reports must be provided with the authority application.	
Arsenic	C4793			Acute promyelocytic leukaemia Induction and consolidation treatment The condition must be characterised by the presence of the t(15:17) translocation or PML/RAR-alpha fusion gene transcript; AND The condition must be relapsed; AND Patient must be arsenic naive at induction.	Compliance with Authority Required procedures - Streamlined Authority Code 4793
	C5997			Acute promyelocytic leukaemia The condition must be characterised by the presence of the t(15:17) translocation or PML/RAR-alpha fusion gene transcript.	Compliance with Authority Required procedures - Streamlined Authority Code 5997
	C6018			Acute promyelocytic leukaemia Induction and consolidation treatment The condition must be characterised by the presence of the t(15:17) translocation or PML/RAR-alpha fusion gene transcript.	Compliance with Authority Required procedures - Streamlined Authority Code 6018
Artemether with lumefantrine	C5999			Confirmed or suspected Plasmodium falciparum malaria	
	C6036			Confirmed or suspected Plasmodium falciparum malaria Patient must be unable to swallow a solid dosage form of artemether with lumefantrine.	
Asciminib	C13923	P13923		Chronic Myeloid Leukaemia (CML)	Compliance with

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Continuing treatment for patients without T315I mutation The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have received initial PBS-subsidised treatment with this drug for this condition; AND Patient must be undergoing first continuing treatment with this drug, demonstrating either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%; OR Patient must be undergoing subsequent continuing treatment with this drug, demonstrating a 12-month response of either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%. A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.	Authority Required procedures - Streamlined Authority Code 13923
	C13925	P13925		Chronic Myeloid Leukaemia (CML) Initial PBS-subsidised treatment for patients with T315I mutation The condition must not be in the blast phase; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must be expressing the T315I mutation confirmed through a bone marrow biopsy pathology report; AND The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND Patient must have failed an adequate trial of at least one tyrosine kinase inhibitor as confirmed through a pathology report from an Approved Pathology Authority; OR Patient must have experienced intolerance, not failure to respond, to at least one tyrosine kinase inhibitor as confirmed through a pathology report from an Approved Pathology Authority. Failure of an adequate trial of a tyrosine kinase inhibitor is defined as: 1. Lack of response defined as either: (i) failure to achieve a haematological response after a minimum of 3 months therapy; or	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive (Ph+) cells; or (iii) failure to achieve or maintain a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy; OR 2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph+ cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR 3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR 4. Development of accelerated phase in a patient previously prescribed a TKI inhibitor for any phase of chronic myeloid leukaemia; OR 5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during TKI therapy in patients with accelerated phase chronic myeloid leukaemia. Accelerated phase is defined by the presence of 1 or more of the following: 1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or 2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or 3. Peripheral basophils greater than or equal to 20%; or 4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or 5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome). The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome;	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				or (ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and (iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation; and (iv) where there has been a loss of response to imatinib or dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib, ponatinib or asciminib at any one time and must not be receiving concomitant interferon alfa therapy Up to a maximum of 18 months of treatment may be authorised under this initial restriction.	
	C13950	P13950		Chronic Myeloid Leukaemia (CML) Initial PBS-subsidised treatment for patients without T315I mutation The treatment must be the sole PBS-subsidised therapy for this condition; AND The condition must not be in the blast phase; AND The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have failed an adequate trial of at least two tyrosine kinase inhibitors; OR Patient must have experienced intolerance, not failure to respond, to at least two tyrosine kinase inhibitors; OR Patient must have failed an adequate trial of at least one tyrosine kinase inhibitor with intolerance to at least another tyrosine kinase inhibitor. Failure of an adequate trial of a tyrosine kinase inhibitor is defined as: 1. Lack of response defined as either: (i) failure to achieve a haematological response after a minimum of 3 months therapy; or (ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive (Ph+) cells; or (iii) failure to achieve or maintain a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy; OR 2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph+ cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR 3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR 4. Development of accelerated phase in a patient previously prescribed a TKI inhibitor for any phase of chronic myeloid leukaemia; OR 5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during TKI therapy in patients with accelerated phase chronic myeloid leukaemia. Accelerated phase is defined by the presence of 1 or more of the following: 1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or 2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or 3. Peripheral basophils greater than or equal to 20%; or	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or 5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).	
	C14008	P14008		Chronic Myeloid Leukaemia (CML) Continuing Treatment for patients with T315I mutation Patient must have received initial PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must be undergoing first continuing treatment with this drug, demonstrating either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%; OR Patient must be undergoing subsequent continuing treatment with this drug, demonstrating a 12-month response of either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%. A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records. The continuing application for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (i) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a major cytogenetic response [see Note explaining definitions of response]; or (ii) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and	Compliance with Authority Required procedures

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				(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib, ponatinib or asciminib at any one time and must not be receiving concomitant interferon alfa therapy	
Asenapine	C4246			Schizophrenia	Compliance with Authority Required procedures - Streamlined Authority Code 4246
	C5719			Bipolar I disorder The treatment must be maintenance therapy; AND The treatment must be as monotherapy.	Compliance with Authority Required procedures - Streamlined Authority Code 5719
	C5773			Acute mania or mixed episodes The condition must be associated with bipolar I disorder; AND The treatment must be limited to up to 6 months per episode.	Compliance with Authority Required procedures - Streamlined Authority Code 5773
Aspirin	C5884			For treatment of a patient identifying as Aboriginal or Torres Strait Islander	
Atazanavir	C4454			HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512			HIV infection Initial Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 4512

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Atazanavir with cobicistat	C4454			HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512			HIV infection Initial Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Atenolol	C4076	P4076		For a patient who is unable to take a solid dose form of atenolol.	
		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
	C14305	P14305		For a patient who is unable to take a solid dose form of atenolol. The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Atezolizumab	C10125			Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment 2 Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy. The condition must be non-squamous type non-small cell lung cancer (NSCLC); AND Patient must have a WHO performance status of 0 or 1; AND Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material; AND Patient must have progressive disease following treatment with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) OR an anaplastic lymphoma	Compliance with Authority Required procedures - Streamlined Authority Code 10125

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				kinase (ALK) tyrosine kinase inhibitor (TKI); AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer.	
	C10206			Extensive-stage small cell lung cancer Initial treatment The condition must be previously untreated; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be in combination with etoposide and a platinum-based antineoplastic drug.	Compliance with Authority Required procedures - Streamlined Authority Code 10206
	C10215			Locally advanced or metastatic non-small cell lung cancer Continuing treatment - 4 weekly treatment regimen Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have stable or responding disease.	Compliance with Authority Required procedures - Streamlined Authority Code 10215
	C10216			Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing first-line treatment of metastatic disease - 3 weekly treatment regimen Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated. Patient must have previously received PBS-subsidised treatment with this drug in this line of treatment; AND Patient must have stable or responding disease.	Compliance with Authority Required procedures - Streamlined Authority Code 10216
	C10257			Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing first-line treatment of metastatic disease, as monotherapy, where concomitant bevacizumab has ceased due to intolerance - 4 weekly treatment regimen Patient must have experienced intolerance to combination treatment with bevacizumab; AND Patient must have previously received PBS-subsidised treatment with this drug in this	Compliance with Authority Required procedures - Streamlined Authority Code 10257

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				line of treatment; AND Patient must have stable or responding disease; AND The treatment must be the sole PBS-subsidised therapy for this condition.	
	C10297			Locally advanced or metastatic non-small cell lung cancer Continuing treatment - 3 weekly treatment regimen Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must have stable or responding disease.	Compliance with Authority Required procedures - Streamlined Authority Code 10297
	C10509			Extensive-stage small cell lung cancer Continuing treatment - 4 weekly treatment regimen The treatment must be as monotherapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 10509
	C10521			Extensive-stage small cell lung cancer Continuing treatment - 3 weekly treatment regimen The treatment must be as monotherapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 10521
	C10917			Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma Continuing treatment of hepatocellular carcinoma - 3 weekly treatment regimen Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated. Patient must have previously received PBS-subsidised treatment with this drug for	Compliance with Authority Required procedures - Streamlined Authority Code 10917

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				this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition. PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time	
	C10939			Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma Initial treatment Patient must be undergoing combination treatment with bevacizumab and atezolizumab until disease progression, unless not tolerated. Patient must have a WHO performance status of 0 or 1; AND Patient must not be suitable for transarterial chemoembolisation; AND Patient must have Child Pugh class A; AND The condition must be untreated with systemic therapy; OR Patient must have developed intolerance to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal.	Compliance with Authority Required procedures - Streamlined Authority Code 10939
	C10972			Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma Continuing treatment where bevacizumab is discontinued - 4 weekly treatment regimen Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition. PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time	Compliance with Authority Required procedures - Streamlined Authority Code 10972
	C13442			Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC) 1,200 mg administered once every 3 weeks Patient must be both: (i) initiating treatment, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy; OR	Compliance with Authority Required procedures - Streamlined

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				Patient must be continuing existing PBS-subsidised treatment with this drug; OR Patient must be both: (i) transitioning from existing non-PBS to PBS subsidised supply of this drug, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated. Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. The treatment must be for the purpose of adjuvant therapy following all of: (i) surgical resection, (ii) platinum-based chemotherapy; AND The condition must have/have had, at treatment commencement, an absence of each of the following gene abnormalities confirmed via tumour material sampling: (i) an activating epidermal growth factor receptor (EGFR) gene mutation, (ii) an anaplastic lymphoma kinase (ALK) gene rearrangement; AND The condition must have/have had, at treatment commencement, confirmation of programmed cell death ligand 1 (PD-L1) expression on at least 50% of tumour cells; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.	Authority Code 13442
	C13443			Locally advanced or metastatic non-small cell lung cancer Initial treatment - 3 weekly treatment regimen Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must have progressed on or after prior platinum based chemotherapy; OR The condition must have progressed after treatment with tepotinib.	Compliance with Authority Required procedures - Streamlined Authority Code 13443

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C13446			Locally advanced or metastatic non-small cell lung cancer Initial treatment - 4 weekly treatment regimen Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The condition must have progressed on or after prior platinum based chemotherapy; OR The condition must have progressed after treatment with tepotinib.	Compliance with Authority Required procedures - Streamlined Authority Code 13446
	C13448			Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment 1 Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy. The condition must be non-squamous type non-small cell lung cancer (NSCLC); AND Patient must not have previously been treated for this condition in the metastatic setting; OR The condition must have progressed after treatment with tepotinib; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.	Compliance with Authority Required procedures - Streamlined Authority Code 13448
	C13451			Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC) 1,680 mg administered once every 4 weeks, or 840 mg every 2 weeks Patient must be both: (i) initiating treatment, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy; OR Patient must be continuing existing PBS-subsidised treatment with this drug; OR Patient must be both: (i) transitioning from existing non-PBS to PBS subsidised	Compliance with Authority Required procedures - Streamlined Authority Code 13451

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				supply of this drug, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated. Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. The treatment must be for the purpose of adjuvant therapy following all of: (i) surgical resection, (ii) platinum-based chemotherapy; AND The condition must have/have had, at treatment commencement, an absence of each of the following gene abnormalities confirmed via tumour material sampling: (i) an activating epidermal growth factor receptor (EGFR) gene mutation, (ii) an anaplastic lymphoma kinase (ALK) gene rearrangement; AND The condition must have/have had, at treatment commencement, confirmation of programmed cell death ligand 1 (PD-L1) expression on at least 50% of tumour cells; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.	
Atomoxetine	C7876			Attention deficit hyperactivity disorder Initial treatment Must be treated by a paediatrician or psychiatrist. The condition must be or have been diagnosed according to the DSM-5 criteria; AND Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR Patient must have experienced adverse reactions of a severity necessitating	Compliance with Authority Required procedures - Streamlined Authority Code 7876

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				permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously). Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.	
	C7890			Attention deficit hyperactivity disorder Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 7890
Atorvastatin		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Atovaquone	C5609			Mild to moderate Pneumocystis carinii pneumonia Patient must be an adult; AND Patient must be intolerant of trimethoprim/sulfamethoxazole therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 5609
Atovaquone with proguanil	C5981			Confirmed or suspected Plasmodium falciparum malaria Patient must be aged 3 years or older. The treatment must be used where quinine containing regimens are inappropriate.	
Avelumab	C8947			Stage IV (metastatic) Merkel Cell Carcinoma Initial treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not exceed a total of 9 doses at a maximum dose of 10 mg per kg every 2 weeks under this restriction. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 8947
	C10023			Stage IV (metastatic) Merkel Cell Carcinoma Continuing treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for	Compliance with Authority Required procedures - Streamlined Authority Code 10023

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				this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must not exceed a maximum dose of 10 mg per kg every 2 weeks under this restriction.	
	C13290			Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer Maintenance therapy - Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 13290
	C13303			Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer Maintenance therapy - Grandfathering treatment Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 October 2022; AND Patient must have received first-line platinum-based chemotherapy prior to initiation of non-PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease following first-line platinum-based chemotherapy; AND Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.	Compliance with Authority Required procedures - Streamlined Authority Code 13303
	C13313			Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer Maintenance therapy - Initial treatment Patient must have received first-line platinum-based chemotherapy; AND	Compliance with Authority Required procedures - Streamlined

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				Patient must not have progressive disease following first-line platinum-based chemotherapy; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Authority Code 13313
Axitinib	C7433	P7433		Stage IV clear cell variant renal cell carcinoma (RCC) Continuing treatment beyond 3 months Patient must have received an initial authority prescription for this drug for this condition; AND Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND The treatment must be the sole PBS-subsidised therapy for this condition. Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.	Compliance with Authority Required procedures - Streamlined Authority Code 7433
	C8588	P8588		Stage IV clear cell variant renal cell carcinoma (RCC) Initial treatment Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor; AND Patient must have a WHO performance status of 2 or less; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.	Compliance with Authority Required procedures
Azacitidine	C14323	P14323		Acute Myeloid Leukaemia	Compliance with Written

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Dose escalation therapy - Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have, in order to extend the dose schedule as per the TGA-approved Product Information, between 5% to 15% blasts in either the: (i) bone marrow, (ii) peripheral blood, in conjunction with clinical assessment; AND Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin. Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail: If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) (c) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating the blast percentage. All reports must be documented in the patient's medical records.	Authority Required procedures
	C14332	P14332		Acute Myeloid Leukaemia Treatment following intensive induction chemotherapy - Initial treatment Patient must have demonstrated either: (i) first complete remission, (ii) complete remission with incomplete blood count recovery following intensive induction chemotherapy; AND Patient must not be a candidate for, including those who choose not to proceed to, haematopoietic stem cell transplantation; AND Patient must have, at the time of induction therapy, a cytogenetic risk classified as either: (i) intermediate-risk, (ii) poor-risk; AND Patient must not have undergone a stem cell transplant; AND Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin. A complete remission is defined as: bone marrow blasts of less than 5%, absence of blasts with Auer rods, absence of extramedullary disease, independent of blood	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				transfusions and a recovery of peripheral blood counts with peripheral neutrophil count greater than 1.0 x 10^{9} /L and platelet count greater than or equal to 100 x 10^{9} /L. A complete remission with incomplete blood count recovery is defined as bone marrow blasts of less than 5%, absence of blasts with Auer rods, absence of extramedullary disease, independent of blood transfusions and a recovery of peripheral blood counts with peripheral neutrophil count less than 1.0 x 10^{9} /L or platelet count less than 100 x 10^{9} /L.	
	C14338	P14338		Acute Myeloid Leukaemia Treatment following intensive induction chemotherapy - Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have, for reasons not attributable to any cause other than AML, no more than 15% blasts in either the: (i) bone marrow, (ii) peripheral blood; AND Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.	Compliance with Authority Required procedures
Azithromycin	C5637	P5637		Trachoma	
	C5718	P5718		Urethritis The condition must be uncomplicated and due to Chlamydia trachomatis.	
	C5772	P5772		Cervicitis The condition must be uncomplicated and due to Chlamydia trachomatis.	
	C6356			Mycobacterium avium complex infection The treatment must be for prophylaxis; AND Patient must be human immunodeficiency virus (HIV) positive; AND Patient must have CD4 cell counts of less than 75 per cubic millimetre.	Compliance with Authority Required procedures - Streamlined Authority Code 6356
	C9604			Mycobacterium avium complex infection The treatment must be for prophylaxis; AND Patient must be human immunodeficiency virus (HIV) positive; AND	Compliance with Authority Required procedures - Streamlined

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				Patient must have CD4 cell counts of less than 75 per cubic millimetre.	Authority Code 9604
Baclofen	C6911			Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord disease.	Compliance with Authority Required procedures - Streamlined Authority Code 6911
	C6925			Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity of cerebral origin.	Compliance with Authority Required procedures - Streamlined Authority Code 6925
	C6939			Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to multiple sclerosis.	Compliance with Authority Required procedures - Streamlined Authority Code 6939
	C6940			Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord injury.	Compliance with Authority Required procedures - Streamlined Authority Code 6940
	C7134			Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to multiple sclerosis.	Compliance with Authority Required procedures - Streamlined Authority Code 7134
	C7148			Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR	Compliance with Authority Required

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				Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord disease.	procedures - Streamlined Authority Code 7148
	C7152			Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity of cerebral origin.	Compliance with Authority Required procedures - Streamlined Authority Code 7152
	C7153			Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord injury.	Compliance with Authority Required procedures - Streamlined Authority Code 7153
	C9488			Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity of cerebral origin.	Compliance with Authority Required procedures - Streamlined Authority Code 9488
	C9489			Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord injury.	Compliance with Authority Required procedures - Streamlined Authority Code 9489
	C9524			Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord disease.	Compliance with Authority Required procedures - Streamlined Authority Code 9524

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	C9525			Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to multiple sclerosis.	Compliance with Authority Required procedures - Streamlined Authority Code 9525
	C9562			Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity of cerebral origin.	Compliance with Authority Required procedures - Streamlined Authority Code 9562
	C9606			Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord disease.	Compliance with Authority Required procedures - Streamlined Authority Code 9606
	C9637			Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to multiple sclerosis.	Compliance with Authority Required procedures - Streamlined Authority Code 9637
	C9638			Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord injury.	Compliance with Authority Required procedures - Streamlined Authority Code 9638
		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Balsalazide	C7621	P7621		Ulcerative colitis	Compliance with

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				Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR Patient must be intolerant to sulfasalazine.	Authority Required procedures - Streamlined Authority Code 7621
	C14306	P14306		Ulcerative colitis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR Patient must be intolerant to sulfasalazine.	Compliance with Authority Required procedures - Streamlined Authority Code 14306
Baricitinib	C14483	P14483		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this	Compliance with Written Authority Required procedures

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				condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major	

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				joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	
	C14486	P14486		Severe active rheumatoid arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L;	Compliance with Written Authority Required procedures

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				AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent	

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				course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14488	P14488		Severe active rheumatoid arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	Compliance with Authority Required procedures
	C14493	P14493		Severe active rheumatoid arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of	Compliance with Written Authority Required procedures

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				rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will	

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				enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14498	P14498		Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose	Compliance with Written Authority Required procedures

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				of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour	

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				and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.	

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				If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14499	P14499		Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.	Compliance with Authority Required procedures - Streamlined Authority Code 14499

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				Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14507	P14507		Severe active rheumatoid arthritis First continuing treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment.	Compliance with Authority Required procedures
Beclometasone	C6348			Asthma Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.	
Beclometasone with formoterol	C11057			Asthma Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids. Patient must be aged 18 years or older.	Compliance with Authority Required procedures - Streamlined Authority Code 11057
Beclometasone with formoterol and	C12349			Chronic obstructive pulmonary disease (COPD) Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12	Compliance with Authority Required procedures - Streamlined

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glycopyrronium				months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition. Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.	Authority Code 12349
	C12603			Severe asthma Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique. Patient must be at least 18 years of age. Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.	Compliance with Authority Required procedures - Streamlined Authority Code 12603
Bendamustine	C7943			Previously untreated stage II bulky or stage III or IV indolent non-Hodgkin's lymphoma Induction treatment The condition must be CD20 positive; AND The condition must be previously untreated; AND The condition must be symptomatic; AND The treatment must be for induction treatment purposes only; AND The treatment must be in combination with rituximab or obinutuzumab; AND The treatment must not exceed 6 cycles (12 doses) with this drug under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 7943

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	C7944			Follicular lymphoma Re-induction treatment The condition must be CD20 positive; AND The condition must be refractory to treatment with rituximab for this condition; AND The condition must be symptomatic; AND The treatment must be for re-induction treatment purposes only; AND The treatment must be in combination with obinutuzumab; AND The treatment must not exceed 6 cycles (12 doses) with this drug under this restriction. The condition is considered rituximab-refractory if the patient experiences less than a partial response or progression of disease within 6 months after completion of a prior rituximab-containing regimen.	Compliance with Authority Required procedures - Streamlined Authority Code 7944
	C7972			Previously untreated stage III or IV mantle cell lymphoma Induction treatment The condition must be CD20 positive; AND The treatment must be in combination with rituximab; AND The condition must be previously untreated; AND The condition must be symptomatic; AND The treatment must be for induction treatment purposes only; AND Patient must not receive more than 6 cycles (12 doses) of treatment under this restriction; AND Patient must not be eligible for stem cell transplantation.	Compliance with Authority Required procedures - Streamlined Authority Code 7972
Benzydamine	C5672	P5672		Mucositis The condition must be radiation induced.	
	C5732			Mucositis The condition must be radiation induced.	
	C6197	P6197		Painful mouth Patient must be receiving palliative care.	Compliance with Authority Required procedures - Streamlined

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					Authority Code 6197
Betaine	C4599			Homocystinuria The treatment must be as adjunctive therapy to current standard care; AND The condition must be treated by or in consultation with a metabolic physician. The name of the specialist must be included in the authority application.	Compliance with Authority Required procedures
Betamethasone	C4924			Corticosteroid-responsive dermatoses	
	C4957	P4957		Corticosteroid-responsive dermatoses	
	C6209			Local intra-articular or peri-articular infiltration	
	C6210			Keloid	
	C6211			Chronic discoid lupus erythematosus	
	C6212			Uveitis	
	C6218	P6218		Corticosteroid-responsive dermatoses The condition must cover 40-60% of the patient's body surface area.	Compliance with Authority Required procedures - Streamlined Authority Code 6218
	C6231	P6231		Corticosteroid-responsive dermatoses The condition must cover >80% of the patient's body surface area.	Compliance with Authority Required procedures - Streamlined Authority Code 6231
	C6232	P6232		Corticosteroid-responsive dermatoses The condition must cover 10-20% of the patient's body surface area.	Compliance with Authority Required procedures - Streamlined Authority Code 6232
	C6237			Keloid	

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	C6246	P6246		Corticosteroid-responsive dermatoses The condition must cover 20-40% of the patient's body surface area.	Compliance with Authority Required procedures - Streamlined Authority Code 6246
	C6253			Alopecia areata	
	C6254			Granulomata The condition must be dermal.	
	C6255			Lichen simplex chronicus	
	C6263	P6263		Corticosteroid-responsive dermatoses The condition must cover 60-80% of the patient's body surface area.	Compliance with Authority Required procedures - Streamlined Authority Code 6263
	C6268			Local intra-articular or peri-articular infiltration	
	C6269			Necrobiosis lipoidica	
	C6281			Lichen planus hypertrophic	
	C6291			Lichen planus hypertrophic	
Bicalutamide	C5729			Metastatic (stage D) carcinoma of the prostate The treatment must be in combination with GnRH (LH-RH) analogue therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 5729
Bictegravir with emtricitabine with tenofovir alafenamide	C4470			HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection.	Compliance with Authority Required procedures - Streamlined Authority Code 4470

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	C4522			HIV infection Initial Patient must be antiretroviral treatment naive.	Compliance with Authority Required procedures - Streamlined Authority Code 4522
Bimatoprost with timolol	C4343			Elevated intra-ocular pressure The condition must have been inadequately controlled with monotherapy; AND Patient must have open-angle glaucoma; OR Patient must have ocular hypertension.	
	C4572			Elevated intra-ocular pressure The condition must have been inadequately controlled with monotherapy; AND Patient must have open-angle glaucoma; OR Patient must have ocular hypertension.	
	C5038			Elevated intra-ocular pressure The condition must have been inadequately controlled with monotherapy; AND Patient must have open-angle glaucoma; OR Patient must have ocular hypertension.	
Bimekizumab	C10807	P10807		Severe chronic plaque psoriasis Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; AND The treatment must be as systemic monotherapy (other than methotrexate); AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. Must be treated by a dermatologist.	Compliance with Authority Required procedures
	C13070	P13070		Severe chronic plaque psoriasis Grandfathered patient - Face, hand, foot or Whole body - Balance of Supply	Compliance with Authority Required

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				Must be treated by a dermatologist. The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must have received insufficient therapy with this drug for this condition under the Grandfathered patient - Whole body restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Grandfathered patient - Face, hand, foot restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.	procedures
	C14374	P14374		Severe chronic plaque psoriasis Initial treatment - Initial 1, Face, hand, foot (new patient) Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the	Compliance with Written Authority Required procedures

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				time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI)	

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				calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C14375	P14375		Severe chronic plaque psoriasis Continuing treatment, Whole body Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.	Compliance with Written Authority Required procedures

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				The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 4 weeks old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14376	P14376		Severe chronic plaque psoriasis Continuing treatment, Face, hand, foot Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND	Compliance with Written Authority Required procedures

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				The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 4 weeks old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this	

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				restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14396	P14396		Severe chronic plaque psoriasis Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised	Compliance with Written Authority Required procedures

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				treatment with this drug, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14412	P14412		Severe chronic plaque psoriasis Grandfathered patient - Whole body (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have a documented severe chronic plaque psoriasis where lesions have been present for at least 6 months prior to commencing non-PBS-subsidised treatment with this drug for this condition; AND Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 October 2023; AND Patient must have a documented failure to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments prior to commencing non-PBS-subsidised treatment with this drug for this condition: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND Patient must have a documented Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing non-PBS-subsidised treatment with this drug for this condition; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheets including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and (c) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. The most recent PASI assessment must be no more than 4 weeks old at the time of	

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				application. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.	
	C14425	P14425		Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C14437	P14437		Severe chronic plaque psoriasis Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14448	P14448		Severe chronic plaque psoriasis Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				face, palm of a hand or sole of a foot; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 4 weeks old at the time of application. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C14449	P14449		Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2,	Compliance with Authority Required

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 24 weeks treatment; AND The treatment must be as systemic monotherapy (other than methotrexate); AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. Must be treated by a dermatologist.	procedures
	C14460	P14460		Severe chronic plaque psoriasis Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C14726	P14726		Severe chronic plaque psoriasis	Compliance with Written

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Grandfathered patient - Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) Patient must have a documented severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where lesions have been present for at least 6 months prior to commencing non-PBS-subsidised treatment with this drug for this condition; AND Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 October 2023; AND Patient must have a documented failure to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments prior to commencing non-PBS-subsidised treatment with this drug for this condition: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND Patient must have had disease, prior to treatment with this drug for this condition, classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling were rated as severe or very severe; or (ii) the skin area affected was 30% or more of the face, palm of a hand or sole of a foot; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.	Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheets including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and (c) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. The most recent PASI assessment must be no more than 4 weeks old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.	
Binimetinib	C10306	P10306		Unresectable Stage III or Stage IV malignant melanoma Continuing treatment Patient must have previously been issued with an authority prescription for this drug; AND Patient must be receiving PBS-subsidised encorafenib concomitantly for this condition; AND Patient must have stable or responding disease.	Compliance with Authority Required procedures - Streamlined Authority Code 10306
	C10328	P10328		Unresectable Stage III or Stage IV malignant melanoma Initial treatment Patient must be receiving PBS-subsidised encorafenib concomitantly for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 10328
Bisacodyl	C5613	P5613		Constipation Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.	

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	C5640	P5640		Constipation Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.	
	C5685	P5685		Anorectal congenital abnormalities	
	C5720	P5720		Constipation Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.	
	C5775	P5775		Constipation Patient must be receiving palliative care.	
	C5776	P5776		Terminal malignant neoplasia	
	C5804	P5804		Megacolon	
	C5819	P5819		Constipation Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult. Patient must identify as Aboriginal or Torres Strait Islander.	
	C5823	P5823		Anorectal congenital abnormalities Patient must identify as Aboriginal or Torres Strait Islander.	
	C5851	P5851		Terminal malignant neoplasia Patient must identify as Aboriginal or Torres Strait Islander.	
	C5866	P5866		Megacolon Patient must identify as Aboriginal or Torres Strait Islander.	
	C5879	P5879		Constipation Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility. Patient must identify as Aboriginal or Torres Strait Islander.	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
Bisoprolol	C5324	P5324		Moderate to severe heart failure Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.	
	C14251	P14251		Moderate to severe heart failure The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.	
Bivalirudin	C4919			Coronary artery disease Patient must be undergoing percutaneous coronary intervention.	Compliance with Authority Required procedures - Streamlined Authority Code 4919
Bleomycin	C6224			Lymphoma	
	C6275			Germ cell neoplasms	
Blinatumomab	C9369			Acute lymphoblastic leukaemia Consolidation treatment Patient must have previously received PBS-subsidised induction treatment with this drug for this condition; AND Patient must have achieved a complete remission; OR Patient must have achieved a complete remission with partial haematological recovery; AND The treatment must not be more than 3 treatment cycles under this restriction in a lifetime; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.	Compliance with Authority Required procedures
	C9519			Acute lymphoblastic leukaemia Induction treatment - balance of supply The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Cooperative Oncology Group (ECOG) performance status of 2 or less; AND The condition must not be present in the central nervous system or testis; AND Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive; AND Patient must have received insufficient therapy with this agent for this condition under the Induction treatment restriction to complete a maximum of 2 treatment cycles in a lifetime. According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 9 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for 4 or more hours), supervision by a health care professional or hospitalisation is recommended. An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 2. Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.	
	C14587			Measurable residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL) Continuing treatment of previously measurable residual disease of Pre-B-cell ALL Must be treated by a physician experienced in the treatment of haematological malignancies. Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND Patient must have achieved a complete remission; AND The condition must be negative for measurable residual disease using the same method used to determine initial PBS eligibility; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND The treatment must not be more than 2 treatment cycles under this restriction in a lifetime. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				recommended. An amount of 784 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle. Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.	
	C14588			Acute lymphoblastic leukaemia Induction treatment The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less; AND The condition must not be present in the central nervous system or testis; AND Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive; AND Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy; AND Patient must not have received more than 1 line of salvage therapy; AND The condition must be one of the following: (i) untreated with this drug for measurable residual disease, (ii) treated with this drug for measurable residual disease, but the condition has not relapsed within 6 months of completing that course of treatment; AND The condition must have more than 5% blasts in bone marrow; AND The treatment must not be more than 2 treatment cycles under this restriction in a lifetime. According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 9 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for 4 or more hours), supervision by a health care professional or hospitalisation is recommended. An amount of 651 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 1. An amount of 784 microgram, which may be	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				obtained under Induction treatment - balance of supply restriction, will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 2. Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and (3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and (4) if applicable, the date of completion of blinatumomab treatment for measurable residual disease and the date of the patient's subsequent relapse; and (5) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application.	
	C14631			Measurable residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL) Initial treatment of measurable residual disease of Pre-B-cell ALL Must be treated by a physician experienced in the treatment of haematological malignancies. Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND The condition must not be present in the central nervous system or testis; AND Patient must have achieved complete remission following intensive combination chemotherapy for initial treatment of acute lymphoblastic leukaemia (ALL) or for subsequent salvage therapy; AND Patient must have measurable residual disease based on measurement in bone marrow, documented after an interval of at least 2 weeks from the last course of systemic chemotherapy given as intensive combination chemotherapy treatment of ALL/as subsequent salvage therapy, whichever was the later, measured using flow cytometry/molecular methods; AND The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended. An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle. Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Measurable residual disease positive Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and (3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy; and (4) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.	
Bortezomib	C11099			Multiple myeloma	
	C13745			Newly diagnosed systemic light chain amyloidosis Administration on Days 1, 8, 15 and 22 of six treatment cycles (28 days per cycle) in total Patient must be undergoing concurrent treatment with PBS-subsidised daratumumab for this PBS indication.	
Botulinum toxin type A purified neurotoxin complex	C5178			Moderate to severe spasticity of the upper limb Patient must have cerebral palsy. Patient must be aged from 2 to 17 years inclusive. Must be treated by a neurologist; OR	Compliance with Authority Required procedures - Streamlined

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				Must be treated by an orthopaedic surgeon; OR Must be treated by a paediatrician; OR Must be treated by a rehabilitation specialist; OR Must be treated by a plastic surgeon.	Authority Code 5178
	C5221			Blepharospasm or hemifacial spasm Patient must have blepharospasm; OR Patient must have hemifacial spasm. Must be treated by a neurologist; OR Must be treated by an ophthalmologist; OR Must be treated by an otolaryngology head and neck surgeon; OR Must be treated by a plastic surgeon. Patient must be aged 12 years or older.	Compliance with Authority Required procedures - Streamlined Authority Code 5221
	C5359			Dynamic equinus foot deformity The condition must be due to spasticity; AND Patient must have cerebral palsy; AND Patient must be ambulant. Patient must be aged from 2 to 17 years inclusive. Must be treated by a neurologist; OR Must be treated by an orthopaedic surgeon; OR Must be treated by a paediatrician; OR Must be treated by a rehabilitation specialist.	Compliance with Authority Required procedures - Streamlined Authority Code 5359
	C5406			Spasmodic torticollis Patient must have spasmodic torticollis; AND The treatment must be as monotherapy; OR The treatment must be as adjunctive therapy to current standard care. Must be treated by a neurologist; OR Must be treated by a plastic surgeon; OR Must be treated by a rehabilitation specialist.	Compliance with Authority Required procedures - Streamlined Authority Code 5406
	C5408			Severe primary axillary hyperhidrosis Patient must have previously failed topical aluminium chloride hexahydrate after one	Compliance with Authority Required

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				to two months of treatment; OR Patient must be intolerant to topical aluminium chloride hexahydrate treatment. Patient must be aged 12 years or older. Must be treated by a dermatologist; OR Must be treated by a neurologist; OR Must be treated by a paediatrician. Maximum number of treatments per year is 3, with no less than 4 months to elapse between treatments.	procedures - Streamlined Authority Code 5408
	C5409			Urinary incontinence The condition must be due to neurogenic detrusor overactivity, as demonstrated by urodynamic study; AND The condition must be inadequately controlled by anti-cholinergic therapy; AND Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with Botulinum Toxin Type A Neurotoxin Complex; AND Patient must be willing and able to self-catheterise; AND The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment; AND Patient must have multiple sclerosis; OR Patient must have a spinal cord injury; OR Patient must be aged 18 years or older and have spina bifida. Must be treated by a urologist; OR Must be treated by a urogynaecologist.	Compliance with Authority Required procedures - Streamlined Authority Code 5409
	C6953			Urinary incontinence Must be treated by a urologist; OR Must be treated by a gynaecologist. The condition must be due to idiopathic overactive bladder; AND The condition must have been inadequately controlled by therapy involving at least two alternative anti-cholinergic agents; AND Patient must experience at least 14 episodes of urinary incontinence per week prior	Compliance with Authority Required procedures - Streamlined Authority Code 6953

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				to commencement of treatment with botulinum toxin type A neurotoxin complex; AND Patient must be willing and able to self-catheterise; AND The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment. Patient must be aged 18 years or older.	
	C8822			Dynamic equinus foot deformity The condition must be due to spasticity; AND Patient must have cerebral palsy; AND Patient must be ambulant. Patient must be aged 18 years or older. Must be treated by a neurologist; OR Must be treated by an orthopaedic surgeon; OR Must be treated by a paediatrician; OR Must be treated by a rehabilitation specialist.	Compliance with Authority Required procedures - Streamlined Authority Code 8822
	C8929			Moderate to severe spasticity of the upper limb Patient must have cerebral palsy. Patient must be aged 18 years or older. Must be treated by a neurologist; OR Must be treated by an orthopaedic surgeon; OR Must be treated by a paediatrician; OR Must be treated by a rehabilitation specialist; OR Must be treated by a plastic surgeon.	Compliance with Authority Required procedures - Streamlined Authority Code 8929
	C9334			Moderate to severe spasticity of the lower limb following an acute event Must be treated by a neurologist; OR Must be treated by an orthopaedic surgeon; OR Must be treated by a rehabilitation specialist; OR Must be treated by a plastic surgeon; OR Must be treated by a geriatrician. The condition must be moderate to severe spasticity of the lower limb/s following stroke or other acute neurological event, defined as a Modified Ashworth Scale rating	Compliance with Authority Required procedures - Streamlined Authority Code 9334

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				of 3 or more; AND The treatment must only be used as second line therapy when standard management has failed; OR The treatment must only be used as an adjunct to physical therapy; AND The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating of at least 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A); AND Patient must not have established severe contracture in the limb to be treated; AND The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per lower limb in the the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per lower limb each year thereafter. Patient must be aged 18 years or older. Standard management includes physiotherapy and/or oral spasticity agents.	
	C9547			Moderate to severe spasticity of the upper limb following an acute event The condition must be moderate to severe spasticity of the upper limb/s following an acute event, defined as a Modified Ashworth Scale rating of 3 or more; AND The treatment must only be used as second line therapy when standard management has failed; OR The treatment must only be used as an adjunct to physical therapy; AND The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A); AND The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per upper limb in the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per upper limb each year thereafter; AND Patient must not have established severe contracture in the limb to be treated. Patient must be aged 18 years or older. Must be treated by a neurologist; OR Must be treated by an orthopaedic surgeon; OR	Compliance with Authority Required procedures - Streamlined Authority Code 9547

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				Must be treated by a rehabilitation specialist; OR Must be treated by a plastic surgeon; OR Must be treated by a geriatrician. Standard management includes physiotherapy and/or oral spasticity agents.	
	C11784			Chronic migraine Must be treated by a neurologist. Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with botulinum toxin type A neurotoxin; AND Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with botulinum toxin type A neurotoxin; AND Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of headache days per month after two treatment cycles (each of 12 weeks duration) in order to be eligible for continuing PBS-subsidised treatment; AND Patient must be appropriately managed by his or her practitioner for medication overuse headache, prior to initiation of treatment with botulinum toxin. Patient must be aged 18 years or older. Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.	Compliance with Authority Required procedures - Streamlined Authority Code 11784
Brentuximab vedotin	C13134			CD30 positive peripheral T-cell lymphoma, non-cutaneous type Initial treatment Patient must have histological confirmation of CD30 expression in at least 3% of malignant cells; AND The treatment must be for first line therapy for this condition; AND The treatment must be for curative intent; AND The treatment must be in combination with cyclophosphamide, doxorubicin and prednisone; AND The treatment must not be more than 6 treatment cycles under this restriction in a lifetime. Applications for authorisation of initial treatment must be made via the Online PBS	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (a) details (date, unique identifying number/code or provider number) of a histology report on the tumour sample from an Approved Pathology Authority showing CD30 positivity of at least 3% malignant cells; and (b) The date of initial diagnosis of Peripheral T-cell lymphoma. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
	C13179			CD30 positive cutaneous T-cell lymphoma Initial treatment Patient must have pathologically confirmed CD30 positive cutaneous T-cell lymphoma; AND Patient must have CD30 positivity of at least 3% of malignant cells; AND Patient must have a diagnosis of mycosis fungoides; OR Patient must have a diagnosis of Sezary syndrome; OR Patient must have a diagnosis of primary cutaneous anaplastic large cell lymphoma; AND Patient must have received prior systemic treatment for this condition; AND The condition must be relapsed or refractory; AND The treatment must not exceed 4 cycles under this restriction in a lifetime; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (a) details (date, unique identifying number/code or provider number) of the histopathology report from an Approved Pathology Authority demonstrating the patient has a diagnosis of either mycosis fungoides, Sezary syndrome or primary cutaneous anaplastic large cell lymphoma; and	Compliance with Written Authority Required procedures

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				(b) details (date, unique identifying number/code or provider number) of a histology report on the tumour sample or of a flow cytometric analysis of lymphoma cells of the blood showing CD30 positivity of at least 3% of malignant cells; and (c) Date of commencement and completion of the most recent prior systemic treatment. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
	C13181			CD30 positive cutaneous T-cell lymphoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have achieved an objective response with this drug; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The treatment must not exceed 12 cycles under this restriction in a lifetime. An objective response is defined as the demonstration of response by clinical observation of skin lesions, or response by positron-emission tomography (PET) and/or computed tomography (CT) standard criteria.	Compliance with Authority Required procedures
	C13182			CD30 positive systemic anaplastic large cell lymphoma Initial treatment The treatment must be for curative intent; AND Patient must have undergone appropriate prior front-line curative intent chemotherapy; AND Patient must demonstrate relapsed or chemotherapy-refractory disease; AND Patient must have responded to PBS-subsidised treatment with this drug if previously	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				used for initial treatment of CD30 positive peripheral T-cell lymphoma, non-cutaneous type; AND The treatment must not exceed 4 cycles under this restriction. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (a) details (date, unique identifying number or provider number) of a histology report showing evidence of the tumour's CD30 positivity; and (b) The date of initial diagnosis of systemic anaplastic large cell lymphoma; and (c) Dates of commencement and completion of front-line curative intent chemotherapy; and (d) a declaration of whether the patient's disease is relapsed or refractory, and the date and means by which the patient's disease was assessed as being relapsed or refractory. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
	C13208			Relapsed or Refractory Hodgkin lymphoma Continuing treatment Patient must have undergone a primary autologous stem cell transplant (ASCT) for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 12 cycles of treatment under this restriction. The treatment must not exceed a total of 16 cycles of combined initial and continuing treatment in a lifetime.	Compliance with Authority Required procedures

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	C13209			Relapsed or Refractory Hodgkin lymphoma Initial treatment Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition; AND Patient must not be suitable for ASCT for this condition; OR Patient must not be suitable for treatment with multi-agent chemotherapy for this condition; AND Patient must have experienced a relapsed CD30+ Hodgkin lymphoma following at least two prior treatments for this condition; OR Patient must have experienced a refractory CD30+ Hodgkin lymphoma following at least two prior treatments for this condition; AND Patient must not receive more than 4 cycles of treatment under this restriction. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail. If the application is submitted through HPOS upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Written Authority Required procedures
	C13212			CD30 positive peripheral T-cell lymphoma, non-cutaneous type Continuing treatment The treatment must be in combination with cyclophosphamide, doxorubicin and prednisone; AND Patient must have completed 6 initial cycles of PBS-subsidised treatment with this drug for this indication; AND Patient must have achieved at least a partial response to the 6 initial cycles of treatment with a combination of this drug and cyclophosphamide, doxorubicin and prednisone for this indication; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must not be more than 2 treatment cycles under this restriction in a	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				lifetime. Partial response is defined using Lugano Response Criteria for Non-Hodgkin Lymphoma as: (a) Positron emission tomography-based response: lymph nodes and extralymphatic sites - a score of 4 (uptake moderately > liver), or 5 (uptake markedly higher than liver and/or new lesions), with reduced uptake compared with baseline and residual mass(es) of any size; nonmeasured lesions - not applicable; organ enlargement - not applicable; new lesions - none; bone marrow - residual uptake higher than uptake in normal marrow but reduced compared with baseline (diffuse uptake compatible with reactive changes from chemotherapy allowed). If there are persistent focal changes in the marrow in the context of a nodal response, consideration should be given to further evaluation with MRI or biopsy or an interval scan; OR (b) Computed tomography-based response: lymph nodes and extralymphatic sites - greater than or equal to 50% decrease in the sum of the product of the perpendicular diameters for multiple lesions, of up to six (6) target measurable nodes and extranodal sites; non-measured lesions - absent/normal, regressed but no increase; new lesions - none; bone marrow - not applicable.	
	C13231			Relapsed or Refractory Hodgkin lymphoma Continuing treatment Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition; AND Patient must not be suitable for ASCT for this condition; OR Patient must not be suitable for treatment with multi-agent chemotherapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 12 cycles of treatment under this restriction. The treatment must not exceed a total of 16 cycles of combined initial and continuing treatment in a lifetime.	Compliance with Authority Required procedures

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	C13259			Relapsed or Refractory Hodgkin lymphoma Initial treatment Patient must have undergone a primary autologous stem cell transplant (ASCT); AND Patient must have experienced a relapsed CD30+ Hodgkin lymphoma post ASCT; OR Patient must have experienced a refractory CD30+ Hodgkin lymphoma post ASCT; AND Patient must not receive more than 4 cycles of treatment under this restriction. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail. If the application is submitted through HPOS upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Written Authority Required procedures
	C13261			CD30 positive systemic anaplastic large cell lymphoma Continuing treatment Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed 12 cycles under this restriction in a lifetime.	Compliance with Authority Required procedures
Brexpiprazole	C4246			Schizophrenia	Compliance with Authority Required procedures - Streamlined Authority Code 4246
Brigatinib	C7346			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment	Compliance with Authority Required procedures

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				The treatment must be as monotherapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.	
	C10384			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment The treatment must be as monotherapy; AND The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND Patient must have a WHO performance status of 2 or less. Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.	Compliance with Authority Required procedures
Brimonidine with timolol	C4343			Elevated intra-ocular pressure The condition must have been inadequately controlled with monotherapy; AND Patient must have open-angle glaucoma; OR Patient must have ocular hypertension.	
	C5038			Elevated intra-ocular pressure The condition must have been inadequately controlled with monotherapy; AND Patient must have open-angle glaucoma; OR Patient must have ocular hypertension.	
Brinzolamide with brimonidine	C5038			Elevated intra-ocular pressure The condition must have been inadequately controlled with monotherapy; AND Patient must have open-angle glaucoma; OR Patient must have ocular hypertension.	
	C5630			Elevated intra-ocular pressure The condition must have been inadequately controlled with monotherapy; AND	

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				Patient must have open-angle glaucoma; OR Patient must have ocular hypertension.	
Brinzolamide with timolol	C4343			Elevated intra-ocular pressure The condition must have been inadequately controlled with monotherapy; AND Patient must have open-angle glaucoma; OR Patient must have ocular hypertension.	
	C5038			Elevated intra-ocular pressure The condition must have been inadequately controlled with monotherapy; AND Patient must have open-angle glaucoma; OR Patient must have ocular hypertension.	
Brivaracetam	C10208			Intractable partial epileptic seizures Continuing treatment Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition; AND The treatment must not be given concomitantly with levetiracetam.	Compliance with Authority Required procedures - Streamlined Authority Code 10208
	C10210			Intractable partial epileptic seizures Initial treatment Must be treated by a neurologist. The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent; AND The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents; AND The treatment must not be given concomitantly with levetiracetam, except for cross titration.	Compliance with Authority Required procedures - Streamlined Authority Code 10210
	C10251			Intractable partial epileptic seizures Initial treatment Must be treated by a neurologist. The treatment must be in combination with two or more anti-epileptic drugs which	Compliance with Authority Required procedures - Streamlined Authority Code 10251

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				includes one second-line adjunctive agent; AND The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents; AND Patient must be unable to take a solid dose form of this drug; AND The treatment must not be given concomitantly with levetiracetam, except for cross titration.	
	C10330			Intractable partial epileptic seizures Continuing treatment Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition; AND Patient must be unable to take a solid dose form of this drug; AND The treatment must not be given concomitantly with levetiracetam.	Compliance with Authority Required procedures - Streamlined Authority Code 10330
Brolucizumab	C13426			Subfoveal choroidal neovascularisation (CNV) Continuing treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. The condition must be due to age-related macular degeneration (AMD); AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.	Compliance with Authority Required procedures
	C13769			Subfoveal choroidal neovascularisation (CNV) Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. The condition must be due to age-related macular degeneration (AMD); AND Patient must have persistent macular exudation, as determined clinically and/or by optical coherence tomography or fluorescein angiography, despite at least 6 months of PBS-subsidised treatment with: 1. Aflibercept and/or 2. Ranibizumab and/or 3. Faricimab; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND	Compliance with Written Authority Required procedures

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				Patient must not have previously received PBS-subsidised treatment with this drug for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. If the application is submitted through HPOS form upload or mail, it must include: (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.	
Bromocriptine	C5172	P5172		Prevention of the onset of lactation The treatment must occur in the puerperium; AND The treatment must be for medical reasons.	
	C6706	P6706		Pathological hyperprolactinaemia Patient must have had surgery for this condition with incomplete resolution.	
	C6707	P6707		Pathological hyperprolactinaemia Patient must be one in whom radiotherapy is not indicated.	
	C6717	P6717		Acromegaly	
	C6718	P6718		Parkinson disease	
	C6719	P6719		Pathological hyperprolactinaemia Patient must have had radiotherapy for this condition with incomplete resolution.	
	C6787	P6787		Pathological hyperprolactinaemia Patient must be one in whom surgery is not indicated.	

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	C14914	P14914		Acromegaly The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
	C14981	P14981		Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have had surgery for this condition with incomplete resolution.	
	C15017	P15017		Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have had radiotherapy for this condition with incomplete resolution.	
	C15028	P15028		Parkinson disease The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
	C15043	P15043		Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be one in whom surgery is not indicated.	
	C15044	P15044		Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be one in whom radiotherapy is not indicated.	
Budesonide	C6340			Severe chronic asthma Patient must require long-term steroid therapy; AND Patient must not be able to use other forms of inhaled steroid therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 6340
	C12607			Mild to moderate Crohn disease	Compliance with

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				The condition must affect the ileum; OR The condition must affect the ascending colon; OR The condition must affect the ileum and ascending colon. The total duration of therapy should be no more than 12 weeks in any single course.	Authority Required procedures - Streamlined Authority Code 12607
	C14608	P14608		Eosinophilic oesophagitis Initial treatment - Induction of remission Patient must have a history of symptoms of oesophageal dysfunction; AND Patient must have eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy confirming the presence of at least 15 eosinophils in at least one high power field (hpf); corresponding to approximately 60 eosinophils per mm^2hpf; AND Patient must not receive more than 90 days of treatment under this restriction. Must be treated by a prescriber who is either: (i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis. Applications for treatment of this condition must be received within 12 weeks of biopsy. Symptoms of oesophageal dysfunction include at least one of the following: dysphasia, odynophagia, transient or self-cleared food impaction, chest pain, epigastric discomfort, vomiting/regurgitation. Diagnostic sensitivity increases with the number of biopsies and can be optimised, where necessary, by taking at least eight biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction). After prescribing the Initial induction treatment with budesonide, a histologic assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing therapy. The histologic assessment should be conducted no later than 2 weeks prior to completing the PBS-subsidised First continuing maintenance treatment course to avoid an interruption of supply for continuing therapy.	Compliance with Authority Required procedures
	C14610	P14610		Eosinophilic oesophagitis	Compliance with

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				First continuing treatment - until remission is confirmed Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug for this condition; AND Patient must not receive more than 36 weeks of treatment under this restriction. Must be treated by a prescriber who is either: (i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis, (iv) medical practitioner who has consulted at least one of the above-mentioned prescriber types. Histologic assessment should be based on the peak eosinophils count derived, where necessary, from the evaluation of at least eight oesophageal biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction). The histologic assessment should, where possible, be performed by, or in consultation with, the same physician or surgeon who confirmed the patient's diagnosis of eosinophilic oesophagitis. This assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing treatment. The histologic assessment should be conducted no later than 2 weeks prior to the patient completing the PBS-subsidised First continuing treatment course to avoid an interruption of supply for continuing therapy. Where a histologic assessment is not undertaken, the patient will not be eligible for ongoing treatment. The result of the histological assessment must be documented in the patient's medical records. First application for the subsequent continuing treatment of this condition must be received within 12 weeks of the histologic assessment.	Authority Required procedures
	C14619	P14619		Eosinophilic oesophagitis Subsequent continuing treatment - Maintenance of remission Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have documented evidence of having achieved histologic remission	Compliance with Authority Required procedures

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				while receiving Initial and First continuing PBS-subsidised treatment with this drug for this condition, defined as a peak eosinophil count of less than 5 eosinophils per high power field (hpf), corresponding to less than 16 eosinophils per mm^2hpf on oesophageal biopsy; AND The condition must not have progressed while being treated with this drug. Must be treated by a prescriber who is either: (i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis, (iv) medical practitioner who has consulted at least one of the above-mentioned prescriber types. Histologic assessment should be based on the peak eosinophils count derived, where necessary, from the evaluation of at least eight oesophageal biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction). The histologic assessment should, where possible, be performed by, or in consultation with, the same physician or surgeon who confirmed the patient's diagnosis of eosinophilic oesophagitis. This assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing treatment. The histologic assessment should be conducted no later than 2 weeks prior to the patient completing the PBS-subsidised First continuing treatment course to avoid an interruption of supply for continuing therapy. Where a histologic assessment is not undertaken, the patient will not be eligible for ongoing treatment. The result of the histological assessment must be documented in the patient's medical records. First application for the subsequent continuing treatment of this condition must be received within 12 weeks of the histologic assessment.	
Budesonide with formoterol	C4380			Asthma Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR	Compliance with Authority Required procedures - Streamlined Authority Code 4380

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy. Patient must be aged 12 years or over.	
	C4397	P4397		Asthma Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist. Patient must be aged 12 years or over.	Compliance with Authority Required procedures - Streamlined Authority Code 4397
	C4404			Asthma Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids. Patient must be aged 12 years or over.	Compliance with Authority Required procedures - Streamlined Authority Code 4404
	C7970	P7970		Asthma Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 7970
	C7979			Asthma Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.	Compliance with Authority Required procedures - Streamlined

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					Authority Code 7979
	C10121			Chronic obstructive pulmonary disease (COPD) Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy; AND Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.	Compliance with Authority Required procedures - Streamlined Authority Code 10121
	C10464	P10464		Mild asthma Patient must have asthma and require an anti-inflammatory reliever therapy; AND Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA). Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.	Compliance with Authority Required procedures - Streamlined Authority Code 10464
	C10482	P10482		Mild asthma Patient must have asthma and require an anti-inflammatory reliever therapy; AND Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA). Patient must be aged 12 years or over. Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.	Compliance with Authority Required procedures - Streamlined Authority Code 10482
	C10538	P10538		Asthma Patient must have failed PBS-subsidised fluticasone proprionate and salmeterol as a fixed dose combination for this condition. Must be treated by a respiratory physician; OR Must be treated by a paediatrician.	Compliance with Authority Required procedures - Streamlined Authority Code 10538
Budesonide with glycopyrronium and formoterol	C12349			Chronic obstructive pulmonary disease (COPD) Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR	Compliance with Authority Required procedures - Streamlined Authority Code 12349

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition. Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.	
Buprenorphine	C10748	P10748		Chronic severe pain Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months The condition must require daily, continuous, long term opioid treatment; AND Patient must have cancer pain; OR Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment: (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or (iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months. Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.	Compliance with Authority Required procedures - Streamlined Authority Code 10748

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				Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).	
	C10752	P10752		Chronic severe pain Continuing PBS treatment after 1 June 2020 Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment: (i) is less than 12 months; or (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months. Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).	Compliance with Authority Required procedures - Streamlined Authority Code 10752
	C10755	P10755		Chronic severe pain	Compliance with

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months The condition must require daily, continuous, long term opioid treatment; AND Patient must have cancer pain; OR Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance. Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).	Authority Required procedures - Streamlined Authority Code 10755
	C11753	P11753		Severe disabling pain Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance. Patient must be undergoing palliative care. Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).	Compliance with Authority Required procedures
	C14075			Opioid dependence Must be treated by a health care professional.	Compliance with Authority Required

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				The treatment must be within a framework of medical, social and psychological treatment.	procedures - Streamlined Authority Code 14075
	C14138			Opioid dependence Must be treated by a health care professional. The treatment must be within a framework of medical, social and psychological treatment; AND Patient must be stabilised on sublingual buprenorphine or buprenorphine/naloxone prior to commencing treatment with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 14138
	C14139			Opioid dependence Must be treated by a health care professional. The treatment must be within a framework of medical, social and psychological treatment; AND Patient must be stabilised on one of the following prior to commencing treatment with this drug for this condition: (i) weekly prolonged release buprenorphine (Buvidal Weekly) (ii) sublingual buprenorphine (iii) buprenorphine/naloxone.	Compliance with Authority Required procedures - Streamlined Authority Code 14139
	C14157			Opioid dependence The treatment must be within a framework of medical, social and psychological treatment. A medical practitioner must request a quantity sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 2 repeats will be authorised. A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.	Compliance with Authority Required procedures - Streamlined Authority Code 14157
Buprenorphine with naloxone	C14074			Opioid dependence The treatment must be within a framework of medical, social and psychological treatment. A medical practitioner must request a quantity sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 2 repeats will be authorised. A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.	Compliance with Authority Required procedures - Streamlined Authority Code 14074

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Bupropion	C6881	P6881		Nicotine dependence Completion of a short-term (9 weeks) course of treatment The treatment must be as an aid to achieving abstinence from smoking; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment; AND Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period. Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.	Compliance with Authority Required procedures - Streamlined Authority Code 6881
	C6882	P6882		Nicotine dependence Commencement of a short-term (9 weeks) course of treatment The treatment must be as an aid to achieving abstinence from smoking; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have indicated they are ready to cease smoking; AND Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period. Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated. Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 6882
Cabazitaxel	C13207			Castration resistant metastatic carcinoma of the prostate The treatment must be in combination with prednisone or prednisolone; AND The condition must be resistant to treatment with docetaxel; OR Patient must have a documented intolerance necessitating permanent treatment withdrawal or a contraindication to docetaxel; AND The treatment must not be used in combination with a novel hormonal drug; AND Patient must have a WHO performance status of 2 or less; AND Patient must not receive PBS-subsidised cabazitaxel if progressive disease develops while on cabazitaxel.	Compliance with Authority Required procedures - Streamlined Authority Code 13207

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Cabergoline	C5136	P5136		Pathological hyperprolactinaemia Patient must be one in whom surgery is not indicated.	
	C5137	P5137		Pathological hyperprolactinaemia Patient must have had surgery for this condition with incomplete resolution.	
	C5168			Parkinson disease	
	C5172	P5172		Prevention of the onset of lactation The treatment must occur in the puerperium; AND The treatment must be for medical reasons.	
	C5357	P5357		Pathological hyperprolactinaemia Patient must have had radiotherapy for this condition with incomplete resolution.	
	C5398	P5398		Pathological hyperprolactinaemia Patient must be one in whom radiotherapy is not indicated.	
	C14918	P14918		Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be one in whom surgery is not indicated.	
	C14959	P14959		Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be one in whom radiotherapy is not indicated.	
	C14983	P14983		Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have had radiotherapy for this condition with incomplete resolution.	
	C15005	P15005		Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum	

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				quantity of this medicine suitable for this patient; AND Patient must have had surgery for this condition with incomplete resolution.	
Cabotegravir	C12619			HIV infection Patient must be virologically suppressed on a stable antiretroviral regimen for at least 6 months; AND The treatment must be in combination with rilpivirine tablets; AND Patient must intend to proceed to treatment with intramuscular administration of cabotegravir and rilpivirine.	Compliance with Authority Required procedures - Streamlined Authority Code 12619
Cabotegravir and rilpivirine	C12636			HIV infection Patient must have previously received PBS-subsidised therapy for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 12636
Cabozantinib	C7631	P7631		Stage IV clear cell variant renal cell carcinoma (RCC) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.	Compliance with Authority Required procedures - Streamlined Authority Code 7631
	C11880	P11880		Stage IV clear cell variant renal cell carcinoma (RCC) Initial treatment The condition must be each of: (i) classified as having an intermediate to poor survival risk score according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), (ii) untreated with a tyrosine kinase inhibitor; OR Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) despite treatment with a tyrosine kinase inhibitor, irrespective of the current IMDC survival risk score; AND Patient must have a WHO performance status of 2 or less; AND	Compliance with Authority Required procedures - Streamlined Authority Code 11880

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				The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be undergoing treatment with this drug for the first time at the time of the first PBS prescription.	
Calcipotriol with betamethasone	C6809	P6809		Chronic stable plaque type psoriasis vulgaris The condition must be inadequately controlled by potent topical corticosteroid monotherapy.	
	C14236	P14236		Chronic stable plaque type psoriasis vulgaris The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be inadequately controlled by potent topical corticosteroid monotherapy.	
Calcitonin salmon	C13886			Hypercalcaemia The treatment must be initiated in a hospital; AND The treatment must be for a patient who cannot tolerate bisphosphonates due to kidney disease.	Compliance with Authority Required procedures
	C13913			Symptomatic Paget disease of bone The treatment must be for a patient who cannot tolerate bisphosphonates due to kidney disease.	Compliance with Authority Required procedures
Calcitriol	C5089	P5089		Hypophosphataemic rickets	Compliance with Authority Required procedures - Streamlined Authority Code 5089
	C5114	P5114		Vitamin D-resistant rickets	Compliance with Authority Required procedures - Streamlined Authority Code 5114
	C5255	P5255		Hypoparathyroidism	Compliance with Authority Required

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					procedures - Streamlined Authority Code 5255
	C5401	P5401		Hypocalcaemia The condition must be due to renal disease.	Compliance with Authority Required procedures - Streamlined Authority Code 5401
	C5402	P5402		Established osteoporosis Patient must have fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.	Compliance with Authority Required procedures - Streamlined Authority Code 5402
	C14231	P14231		Hypophosphataemic rickets The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	Compliance with Authority Required procedures - Streamlined Authority Code 14231
	C14259	P14259		Established osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 14259

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				A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.	
	C14287	P14287		Hypoparathyroidism The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	Compliance with Authority Required procedures - Streamlined Authority Code 14287
	C14296	P14296		Vitamin D-resistant rickets The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	Compliance with Authority Required procedures - Streamlined Authority Code 14296
	C14322	P14322		Hypocalcaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be due to renal disease.	Compliance with Authority Required procedures - Streamlined Authority Code 14322
Calcium	C4586	P4586		Hyperphosphataemia The condition must be associated with chronic renal failure.	Compliance with Authority Required procedures - Streamlined Authority Code 4586
	C14228	P14228		Hyperphosphataemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be associated with chronic renal failure.	Compliance with Authority Required procedures - Streamlined Authority Code 14228
Candesartan		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Candesartan with	C4374	P4374		Hypertension The treatment must not be for the initiation of anti-hypertensive therapy; AND	

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hydrochlorothiazide				The condition must be inadequately controlled with an angiotensin II antagonist; OR The condition must be inadequately controlled with a thiazide diuretic.	
	C14255	P14255		Hypertension The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an angiotensin II antagonist; OR The condition must be inadequately controlled with a thiazide diuretic.	
Cannabidiol	C11681			Severe myoclonic epilepsy in infancy (Dravet syndrome) Patient must have (as an initiating patient)/have had (as a continuing patient), generalised tonic-clonic seizures or generalised clonic seizures that are not adequately controlled with at least two other anti-epileptic drugs; AND The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs. Must be treated by a neurologist if treatment is being initiated; OR Must be treated by a neurologist if treatment is being continued or re-initiated; OR Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; OR Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued.	Compliance with Authority Required procedures
	C14047			Seizures of the Lennox-Gastaut syndrome Patient must have a diagnosis of Lennox-Gastaut syndrome confirmed by an electroencephalogram (EEG) that showed a pattern of slow (less than 3.0 hertz) spike-and-wave discharges with generalised paroxysmal fast activity (sleep recording should be obtained where it is possible); AND Patient must have (as an initiating patient)/have had (as a continuing patient) more than one type of generalised seizures; AND Patient must have had at least two drop seizures (atonic, tonic or tonic-clonic) per week that are not adequately controlled with at least two other anti-epileptic drugs prior to initiating treatment with this medicine; AND The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs. Must be treated by a neurologist if treatment is being initiated; OR	Compliance with Authority Required procedures

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				Must be treated by a neurologist if treatment is being continued or re-initiated; OR Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; OR Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued. Tonic seizures must have been recorded on video-EEG or have been clearly observed and reported by a witness. Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.	
Captopril	C4996			Patients unable to take a solid dose form of an ACE inhibitor.	
Carbamazepine		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Carbimazole		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Carbohydrate, fat, vitamins, minerals and trace elements	C4438			Proven inborn errors of protein metabolism Patient must be unable to meet their energy requirements with permitted food and formulae.	
Carbohydrate, fat, vitamins, minerals and trace elements and supplemented with arachidonic acid and docosahexaenoic acid	C4438			Proven inborn errors of protein metabolism Patient must be unable to meet their energy requirements with permitted food and formulae.	
Carbomer	C6153	P6153		Severe dry eye syndrome, including Sjogren's syndrome	
	C6172			Severe dry eye syndrome	Compliance with Authority Required

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				Patient must be sensitive to preservatives in multi-dose eye drops.	procedures - Streamlined Authority Code 6172
	C6185	P6185		Severe dry eye syndrome, including Sjogren's syndrome Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	
Carbomer 974	C6172			Severe dry eye syndrome Patient must be sensitive to preservatives in multi-dose eye drops.	Compliance with Authority Required procedures - Streamlined Authority Code 6172
Carfilzomib	C12694			Multiple myeloma Initial treatment - once weekly treatment regimen The condition must be confirmed by a histological diagnosis; AND The treatment must be in combination with dexamethasone; AND Patient must have progressive disease after at least one prior therapy; AND Patient must have undergone or be ineligible for a stem cell transplant; AND Patient must not have previously received this drug for this condition; AND Patient must not receive more than three cycles of treatment under this restriction. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft	Compliance with Authority Required procedures - Streamlined Authority Code 12694

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				tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	
	C12849			Multiple myeloma Continuing treatment - once weekly treatment regimen Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with dexamethasone; AND Patient must not develop disease progression while receiving treatment with this drug for this condition; AND Patient must not receive more than 3 cycles of treatment per continuing treatment course authorised under this restriction. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	Compliance with Authority Required procedures - Streamlined Authority Code 12849

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C12930			Multiple myeloma Continuing treatment - twice weekly treatment regimen Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with dexamethasone; AND Patient must not develop disease progression while receiving treatment with this drug for this condition; AND Patient must not receive more than 3 cycles of treatment per continuing treatment course authorised under this restriction. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	Compliance with Authority Required procedures - Streamlined Authority Code 12930
	C12934			Multiple myeloma Initial treatment - twice weekly treatment regimen The condition must be confirmed by a histological diagnosis; AND The treatment must be in combination with dexamethasone; AND Patient must have progressive disease after at least one prior therapy; AND	Compliance with Authority Required procedures - Streamlined Authority Code 12934

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have undergone or be ineligible for a stem cell transplant; AND Patient must not have previously received this drug for this condition; AND Patient must not receive more than three cycles of treatment under this restriction. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	
	C14363			Relapsed and/or refractory multiple myeloma Continuing treatment for Cycles 3 to 12 Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with lenalidomide and dexamethasone; AND Patient must not have progressive disease while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an	Compliance with Authority Required procedures - Streamlined Authority Code 14363

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	
	C14364			Relapsed and/or refractory multiple myeloma Continuing treatment for Cycles 13 onwards Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with lenalidomide and dexamethasone; AND Patient must not have progressive disease while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression	Compliance with Authority Required procedures - Streamlined Authority Code 14364

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	
	C14389			Relapsed and/or refractory multiple myeloma Initial treatment for Cycles 1 to 3 The condition must be confirmed by a histological diagnosis; AND The treatment must be in combination with lenalidomide and dexamethasone; AND Patient must have progressive disease after at least one prior therapy; AND Patient must not have previously received this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Provide details of the histological diagnosis of multiple myeloma, prior treatments	Compliance with Authority Required procedures - Streamlined Authority Code 14389

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				including name(s) of drug(s) and date of the most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response once only through the Authority application for lenalidomide.	
Cariprazine	C4246			Schizophrenia	Compliance with Authority Required procedures - Streamlined Authority Code 4246
Carmellose	C6073	P6073		Severe dry eye syndrome, including Sjogren's syndrome	
	C6098	P6098		Severe dry eye syndrome, including Sjogren's syndrome Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	
	C6120			Severe dry eye syndrome, including Sjogren's syndrome	
	C6172			Severe dry eye syndrome Patient must be sensitive to preservatives in multi-dose eye drops.	Compliance with Authority Required procedures - Streamlined Authority Code 6172
Carmellose with glycerin	C6079	P6079		Severe dry eye syndrome, including Sjogren's syndrome Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	
	C6097	P6097		Severe dry eye syndrome, including Sjogren's syndrome	
Carmustine	C6056			Glioblastoma multiforme The condition must be suspected or confirmed at the time of initial surgery.	
Carvedilol	C5324	P5324		Moderate to severe heart failure	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.	
	C5394	P5394		Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002	
	C14251	P14251		Moderate to severe heart failure The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.	
	C14270	P14270		Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Cefalexin		P4243	CN4243	Prophylaxis of urinary tract infection	Compliance with Authority Required procedures - Streamlined Authority Code 4243
		P6188	CN6188	Osteomyelitis	Compliance with Authority Required procedures - Streamlined Authority Code 6188
		P10410	CN10410	Infection Patient must have a pin-site infection; OR Patient must have an infection following cardiac device insertion; OR Patient must have acute otitis externa; OR Patient must have streptococcal pharyngitis or tonsillitis; OR Patient must have mastitis; OR Patient must have periorbital (preseptal) cellulitis; OR Patient must have acute rheumatic fever; OR Patient must have a diabetic foot infection; OR	Compliance with Authority Required procedures - Streamlined Authority Code 10410

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have a widespread infection of dermatitis; OR Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection; OR Patient must have impetigo; OR Patient must have pyelonephritis; OR Patient must have a condition requiring prolonged oral antibiotic therapy. Midwives may prescribe under this item for the treatment of mastitis only.	
		P10412	CN10412	Infection Patient must have impaired renal function; AND Patient must have a pin-site infection; OR Patient must have an infection following cardiac device insertion; OR Patient must have acute otitis externa; OR Patient must have streptococcal pharyngitis or tonsillitis; OR Patient must have mastitis; OR Patient must have periorbital (preseptal) cellulitis; OR Patient must have acute rheumatic fever; OR Patient must have a diabetic foot infection; OR Patient must have a widespread infection of dermatitis; OR Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection; OR Patient must have impetigo; OR Patient must have pyelonephritis; OR Patient must have a condition requiring prolonged oral antibiotic therapy. Midwives may prescribe under this item for the treatment of mastitis only, where the patient has impaired renal function.	Compliance with Authority Required procedures - Streamlined Authority Code 10412
Cefazolin	C5826			Septicaemia, suspected	
	C5861			Septicaemia, suspected	
	C5867			Cellulitis	
	C5881			Infection where positive bacteriological evidence confirms that this antibiotic is an	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				appropriate therapeutic agent	
	C5882			Septicaemia, proven	
	C5883			Cellulitis	
	C5890			Septicaemia, proven	
	C5891			Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent	
Cefepime	C5842			Febrile neutropenia	Compliance with Authority Required procedures
Cefotaxime	C5826			Septicaemia, suspected	
	C5881			Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent	
	C5890			Septicaemia, proven	
	C5905			Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent	
Ceftriaxone	C5826	P5826		Septicaemia, suspected	
	C5830			Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent	
	C5855	P5855		Gonorrhoea	
	C5862			Septicaemia, proven	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C5868			Septicaemia, suspected	
	C5881	P5881		Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent	
	C5890	P5890		Septicaemia, proven	
Celecoxib	C4907			Rheumatoid arthritis The treatment must be for symptomatic treatment.	
	C4962			Osteoarthritis The treatment must be for symptomatic treatment.	
Cemiplimab	C13322			Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have received non-PBS-subsidised therapy with this drug for this condition prior to 1 November 2022; AND The condition must be unsuitable for each of: (i) curative surgical resection, (ii) curative radiotherapy; AND Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first: (i) disease progression despite treatment with this drug, (ii) 24 months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.	Compliance with Authority Required procedures
	C13373			Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment - 3 weekly treatment regimen Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority Code 13373

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under both initial and continuing treatment restrictions, whichever comes first.	
	C13411			Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) Continuing treatment Patient must have previously received PBS-subsidised therapy with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first: (i) disease progression despite treatment with this drug, (ii) 24 months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.	Compliance with Authority Required procedures
	C13419			Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) Initial treatment covering the first 3 treatment cycles The condition must be unsuitable for each of: (i) curative surgical resection, (ii) curative radiotherapy; AND Patient must have had a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures
	C13766			Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment - 3 weekly treatment regimen Patient must not have previously been treated for this condition in the metastatic setting; OR The condition must have progressed after treatment with tepotinib; AND Patient must not have received prior treatment with a programmed cell death 1 (PD-1) inhibitor or a programmed cell death ligand 1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND The condition must express programmed cell death ligand 1 (PD-L1) with a tumour proportion score (TPS) of at least 50% in the tumour sample.	Compliance with Authority Required procedures - Streamlined Authority Code 13766

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The treatment must not exceed a total of 7 doses under this restriction.	
Ceritinib	C6732			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment The treatment must be as monotherapy; AND The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND Patient must have a WHO performance status of 2 or less. Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.	Compliance with Authority Required procedures
	C7369			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be as monotherapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures
Certolizumab pegol	C9063	P9063		Severe psoriatic arthritis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Must be treated by a rheumatologist; OR	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.	
	C9073	P9073		Severe psoriatic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include:	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9074	P9074		Severe psoriatic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a rheumatologist; OR	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C9105	P9105		Severe psoriatic arthritis Continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older.	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be	

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9183	P9183		Severe psoriatic arthritis Initial treatment - Initial 1 (new patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:	Compliance with Written Authority Required procedures

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				an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C9185	P9185		Severe psoriatic arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment; AND The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.	
	C9431	P9431		Ankylosing spondylitis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	Compliance with Authority Required procedures
	C9625	P9625		Ankylosing spondylitis Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment; AND The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	
	C10431	P10431		Non-radiographic axial spondyloarthritis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug for this condition; AND The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction. The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C10459	P10459		Non-radiographic axial spondyloarthritis Initial 1 (New patient), Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment; AND The treatment must provide no more than the balance of up to 20 weeks treatment. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.	Compliance with Authority Required procedures
	C10513	P10513		Non-radiographic axial spondyloarthritis Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The following must be provided at the time of application and documented in the patient's medical records: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.	
	C11386	P11386		Non-radiographic axial spondyloarthritis	Compliance with Written

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Initial treatment - Initial 1 (New patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.	Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The authority must be made in writing and application must include: (a) a completed authority prescription form(s); and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The baseline BASDAI score and CRP level must also be documented in the patient's medical records.	
	C12392	P12392		Non-radiographic axial spondyloarthritis Continuing treatment - balance of supply	Compliance with Authority Required

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.	procedures
	C14191	P14191		Non-radiographic axial spondyloarthritis Initial treatment - Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or	Compliance with Authority Required procedures

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				(b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The following must be provided at the time of application and documented in the patient's medical records: (a) the BASDAI score; and (b) the C-reactive protein (CRP) level.	
	C14493	P14493		Severe active rheumatoid arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14499	P14499		Severe active rheumatoid arthritis	Compliance with

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be	Authority Required procedures - Streamlined Authority Code 14499

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				used to determine response. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14507	P14507		Severe active rheumatoid arthritis First continuing treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment.	Compliance with Authority Required procedures
	C14542	P14542		Severe active rheumatoid arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR Patient must have received insufficient therapy with this drug for this condition under	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; AND The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.	
	C14571	P14571		Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be at least 18 years of age. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease	

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				and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14591	P14591		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in	Compliance with Written Authority Required

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be at least 18 years of age. Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of	procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	
	C14622	P14622		Severe active rheumatoid arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14659	P14659		Ankylosing spondylitis	Compliance with Written

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a	Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment	

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				failure.	
	C14686	P14686		Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include:	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14692	P14692		Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14714	P14714		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
Cetrorelix	C5046			Assisted Reproductive Technology The treatment must be for prevention of premature luteinisation and ovulation; AND Patient must be undergoing controlled ovarian stimulation; AND Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.	Compliance with Authority Required procedures - Streamlined Authority Code 5046

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
Cetuximab	C4785			Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx Initial treatment The treatment must be in combination with radiotherapy; AND Patient must be unable to tolerate cisplatin.	Compliance with Authority Required procedures - Streamlined Authority Code 4785
	C4788			Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx Continuing treatment The treatment must be in combination with radiotherapy; AND Patient must be unable to tolerate cisplatin; OR Patient must have a contraindication to cisplatin according to the TGA-approved Product Information.	Compliance with Authority Required procedures - Streamlined Authority Code 4788
	C4794			Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx Initial treatment The treatment must be for the week prior to radiotherapy; AND Patient must have a contraindication to cisplatin according to the TGA-approved Product Information.	Compliance with Authority Required procedures - Streamlined Authority Code 4794
	C4908			Metastatic colorectal cancer Initial treatment Patient must have RAS wild-type metastatic colorectal cancer; AND Patient must have a WHO performance status of 0 or 1; AND The condition must be previously untreated; AND The treatment must be in combination with first-line chemotherapy; AND The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 4908
	C4912			Metastatic colorectal cancer Continuing treatment Patient must have received an initial authority prescription for this drug for first-line treatment of RAS wild-type metastatic colorectal cancer; AND Patient must not have progressive disease; AND The treatment must be in combination with first-line chemotherapy; AND	Compliance with Authority Required procedures - Streamlined Authority Code 4912

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.	
	C12016			Metastatic colorectal cancer Continuing treatment Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of first-line chemotherapy; OR Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of treatment with first-line pembrolizumab for dMMR mCRC; AND Patient must not have progressive disease; AND The treatment must be as monotherapy; OR The treatment must be in combination with chemotherapy; AND The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition. Patients who have progressive disease on panitumumab are not eligible to receive PBS-subsidised cetuximab. Patients who have developed intolerance to panitumumab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised cetuximab.	Compliance with Authority Required procedures - Streamlined Authority Code 12016
	C12045			Metastatic colorectal cancer Initial treatment Patient must have RAS wild-type metastatic colorectal cancer; AND Patient must have a WHO performance status of 2 or less; AND The condition must have failed to respond to first-line chemotherapy; OR The condition must have progressed following first-line treatment with pembrolizumab for dMMR mCRC; AND The treatment must be as monotherapy; OR The treatment must be in combination with chemotherapy; AND The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition. Patients who have progressive disease on panitumumab are not eligible to receive	Compliance with Authority Required procedures - Streamlined Authority Code 12045

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				PBS-subsidised cetuximab. Patients who have developed intolerance to panitumumab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised cetuximab.	
	C12470	P12470		Metastatic colorectal cancer Continuing treatment The treatment must be in combination with PBS-subsidised encorafenib for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 12470
	C12483	P12483		Metastatic colorectal cancer Initial treatment The treatment must be in combination with PBS-subsidised encorafenib for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 12483
Chloramphenicol	C5835			For treatment of a patient identifying as Aboriginal or Torres Strait Islander	
Chlortalidone		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Choriogonadotropin alfa	C14096			Infertility indications other than that of Assisted Reproductive Technology Patient must not be undergoing treatment with medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule; AND Patient must not be undergoing simultaneous treatment with this drug through another PBS program listing; AND Must be treated by an obstetrician/gynaecologist; OR Must be treated by a specialist in reproductive endocrinology/infertility; OR Must be treated by a urogynaecologist; OR Must be treated by an endocrinologist; OR Must be treated by a urologist. The PBS prescription, whether it is to initiate or continue treatment, must be made out under the specialist's prescriber number.	
	C14124			Assisted Reproductive Technology Patient must be receiving medical services as described in items 13200, 13201,	Compliance with Authority Required

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				13202 or 13203 of the Medicare Benefits Schedule. Patient must not be undergoing simultaneous treatment with this drug through another PBS program listing.	procedures - Streamlined Authority Code 14124
Chorionic gonadotrophin	C6979			Combined deficiency of human growth hormone and gonadotrophins Patient must be male. Patient must be one in whom the absence of secondary sexual characteristics indicates a lag in maturation.	
	C6987			Infertility Patient must be male. The condition must be due to hypogonadotrophic hypogonadism.	
	C6989			Anovulatory infertility	
	C6990			Infertility Patient must be male. The condition must be associated with isolated luteinising hormone deficiency.	
	C6991			Assisted Reproductive Technology Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.	Compliance with Authority Required procedures - Streamlined Authority Code 6991
	C6995			Hypogonadism or delayed puberty Patient must be male; AND Patient must be aged 16 years or older. Patient must show clinical evidence of the condition; AND The treatment must not extend beyond 6 months.	
Ciclosporin	C6628			Management of transplant rejection The treatment must be used by organ or tissue transplant recipients.	Compliance with Authority Required procedures - Streamlined Authority Code 6628

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
		P6631	CN6631	Nephrotic syndrome Management (initiation, stabilisation and review of therapy) Patient must have failed prior treatment with steroids and cytostatic drugs; OR Patient must be intolerant to treatment with steroids and cytostatic drugs; OR The condition must be considered inappropriate for treatment with steroids and cytostatic drugs; AND Patient must not have renal impairment. Must be treated by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6631
		P6638	CN6638	Severe active rheumatoid arthritis Management (initiation, stabilisation and review of therapy) The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); OR The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate). Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6638
		P6643	CN6643	Management of transplant rejection Management (initiation, stabilisation and review of therapy) Patient must have had an organ or tissue transplantation; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 6643
		P6660	CN6660	Severe atopic dermatitis Management (initiation, stabilisation and review of therapy) Must be treated by a dermatologist; OR Must be treated by a clinical immunologist. The condition must be ineffective to other systemic therapies; OR The condition must be inappropriate for other systemic therapies.	Compliance with Authority Required procedures - Streamlined Authority Code 6660
		P9694	CN9694	Nephrotic syndrome Management (initiation, stabilisation and review of therapy) Patient must have failed prior treatment with steroids and cytostatic drugs; OR	Compliance with Authority Required procedures - Streamlined

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				Patient must be intolerant to treatment with steroids and cytostatic drugs; OR The condition must be considered inappropriate for treatment with steroids and cytostatic drugs; AND Patient must not have renal impairment. Must be treated by a nephrologist.	Authority Code 9694
		P9695	CN9695	Severe atopic dermatitis Management (initiation, stabilisation and review of therapy) Must be treated by a dermatologist; OR Must be treated by a clinical immunologist. The condition must be ineffective to other systemic therapies; OR The condition must be inappropriate for other systemic therapies.	Compliance with Authority Required procedures - Streamlined Authority Code 9695
		P9742	CN9742	Severe active rheumatoid arthritis Management (initiation, stabilisation and review of therapy) The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); OR The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate). Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9742
		P9764	CN9764	Management of transplant rejection Management (initiation, stabilisation and review of therapy) Patient must have had an organ or tissue transplantation; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9764
	C9831			Management of transplant rejection The treatment must be used by organ or tissue transplant recipients.	Compliance with Authority Required procedures - Streamlined Authority Code 9831
		P13122	CN13122	Severe psoriasis Management (initiation, stabilisation and review of therapy)	Compliance with Authority Required

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				The condition must be ineffective to other systemic therapies; OR The condition must be inappropriate for other systemic therapies; AND The condition must have caused significant interference with quality of life. Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist.	procedures - Streamlined Authority Code 13122
		P13168	CN13168	Severe psoriasis Management (initiation, stabilisation and review of therapy) The condition must be ineffective to other systemic therapies; OR The condition must be inappropriate for other systemic therapies; AND The condition must have caused significant interference with quality of life. Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist.	Compliance with Authority Required procedures - Streamlined Authority Code 13168
	C14026			Chronic severe dry eye disease with keratitis Initial treatment for up to the first 180 days of treatment Patient must have a corneal fluorescein staining (CFS) grade of 4 at treatment initiation, using at least one of: (i) the Oxford scale, (ii) the modified Oxford scale, (iii) an equivalent scale to the Oxford scale as determined by the prescriber; AND Patient must have an ocular surface disease index (OSDI) score of at least 23 at treatment initiation; AND The condition must be inadequately controlled by monotherapy with a preservative free artificial tears substitute; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be undergoing simultaneous treatment with a preservative free artificial tears substitute; AND Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; OR Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines; AND Patient must not be undergoing treatment with this drug under this treatment phase beyond day 180 of treatment. Patient must be at least 18 years of age.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Prescribing instruction: State in the first authority application for this drug, for the purpose of having a baseline measurement to assess response to treatment under the Continuing treatment listing, each of: (i) the qualifying corneal fluorescein staining grade (a numerical value no less than 4), (ii) the qualifying ocular surface disease index score (a numerical value no less than 23).	
	C14032			Chronic severe dry eye disease with keratitis Continuing treatment Patient must have received PBS-subsidised treatment with this drug for this condition; AND The condition must have improved to an extent that corneal fluorescein staining, using the same scale used at the time of the first authority application, shows an improvement (reduction) by at least 3 grades from baseline (the grade stated in the first authority application) - the improvement need only be demonstrated by staining once only with the first Continuing treatment authority application; AND The condition must have improved to an extent that the patient's ocular surface disease index score at the time of this authority application, has improved (reduced) by at least 30% compared to the value stated in the first authority application (i.e. baseline); AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; OR Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines. Prescribing instructions: State in the first continuing treatment authority application for this drug: (i) an improved corneal fluorescein staining grade (a numerical value that has improved by 3 grades from that provided in the first Initial 1 treatment authority application). State in all continuing treatment authority applications: (ii) the ocular surface disease index score at the time of this authority application (a numerical value that is at least 30% lower than that stated in the first Initial 1	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				treatment authority application).	
		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Cinacalcet	C10063			Secondary hyperparathyroidism Continuing treatment Must be treated by a nephrologist. Patient must have chronic kidney disease; AND Patient must be on dialysis; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition. During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration. During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and tolerability.	Compliance with Authority Required procedures - Streamlined Authority Code 10063
	C10067			Secondary hyperparathyroidism Continuing treatment Must be treated by a nephrologist. Patient must have chronic kidney disease; AND Patient must be on dialysis; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition. During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration. During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and	Compliance with Authority Required procedures - Streamlined Authority Code 10067

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				tolerability.	
	C10068			Secondary hyperparathyroidism Continuing treatment Patient must have chronic kidney disease; AND Patient must be on dialysis; AND Patient must have achieved a decrease of at least 30% in intact parathyroid hormone (iPTH) concentrations after 6 months treatment; OR Patient must have an intact parathyroid (iPTH) concentration greater than 15 pmol/L and an (adjusted) serum calcium concentration of less than 2.6 mmol/L after 6 months. During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration. During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and tolerability.	Compliance with Authority Required procedures - Streamlined Authority Code 10068
	C10073			Secondary hyperparathyroidism Initial treatment Must be treated by a nephrologist. Patient must have chronic kidney disease; AND Patient must be on dialysis; AND Patient must have failed to respond to conventional therapy; AND Patient must have sustained hyperparathyroidism with iPTH of at least 50 pmol per L; OR Patient must have sustained hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L and an (adjusted) serum calcium concentration at least 2.6 mmol per L. During the titration phase, intact PTH (iPTH) should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved.	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				During the titration phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.	
Ciprofloxacin	C4181			Bacterial keratitis Must be treated by an ophthalmologist or in consultation with an ophthalmologist.	Compliance with Authority Required procedures
	C4195			Bacterial keratitis Must be treated by an ophthalmologist or in consultation with an ophthalmologist.	Compliance with Authority Required procedures
	C5535			Chronic suppurative otitis media Patient must be less than 18 years of age. Patient must have a grommet in situ.	Compliance with Authority Required procedures
	C5551			Chronic suppurative otitis media Patient must be less than 18 years of age. Patient must have perforation of the tympanic membrane.	Compliance with Authority Required procedures
	C5593			Chronic suppurative otitis media Patient must be an Aboriginal or a Torres Strait Islander person; AND Patient must be aged 1 month or older.	Compliance with Authority Required procedures
	C5614			Bone or joint infection The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.	Compliance with Authority Required procedures
	C5615			Prostatitis The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR The condition must be suspected or proven to be caused by gram-positive bacteria	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				resistant to all other appropriate antimicrobials.	
	C5666			Gonorrhoea	Compliance with Authority Required procedures
	C5687			Respiratory tract infection The condition must be proven or suspected to be caused by Pseudomonas aeruginosa; AND Patient must be severely immunocompromised.	Compliance with Authority Required procedures
	C5688			Infection The condition must be proven to be due to Pseudomonas aeruginosa resistant to all other oral antimicrobials; OR The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.	Compliance with Authority Required procedures
	C5689			Epididymo-orchitis The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.	Compliance with Authority Required procedures
	C5722			Bacterial gastroenteritis Patient must be severely immunocompromised.	Compliance with Authority Required procedures
	C5780			Perichondritis of the pinna The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.	Compliance with Authority Required procedures
Citalopram	C4755			Major depressive disorders	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
Citrulline	C5984			Urea cycle disorders The treatment must be for preventing low plasma arginine levels; OR The treatment must be for preventing low citrulline levels.	
Citrulline with carbohydrate	C6683			Urea cycle disorders The treatment must be for preventing low plasma arginine levels; OR The treatment must be for preventing low citrulline levels.	
Cladribine	C6265			Hairy cell leukaemia	Compliance with Authority Required procedures - Streamlined Authority Code 6265
	C10170			Relapsing remitting multiple sclerosis Initial treatment The condition must be diagnosed by a neurologist; AND The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support). Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. The prescriber should write authority prescriptions for the appropriate combination of packs (1, 4 or 6 tablets) to provide sufficient drug for a treatment week based on the weight of the patient in accordance with the TGA approved Product Information.	Compliance with Authority Required procedures - Streamlined Authority Code 10170

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1.	
	C10171			Relapsing remitting multiple sclerosis Continuing treatment Must be treated by a neurologist. The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not show continuing progression of disability while on treatment with this drug; AND Patient must have demonstrated compliance with, and an ability to tolerate, this therapy. The prescriber should request authority approval for the appropriate combination of packs (1, 4 or 6 tablets) to provide sufficient drug for a treatment week based on the weight of the patient in accordance with the TGA approved Product Information. Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1.	Compliance with Authority Required procedures - Streamlined Authority Code 10171
Clarithromycin	C5638			Bordetella pertussis	
	C5663			Atypical mycobacterial infections	
Clindamycin	C5470			Gram-positive coccal infections The condition must not be able to be safely and effectively treated with a penicillin.	
	C5487			Gram-positive coccal infections The condition must not be able to be safely and effectively treated with a penicillin.	
Clobetasol	C5461			Moderate to severe scalp psoriasis The condition must be inadequately controlled with either a vitamin D analogue or	Compliance with Authority Required

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				potent topical corticosteroid as monotherapy; OR The condition must be inadequately controlled with combination use of a vitamin D analogue and potent topical corticosteroid. Patient must be aged 18 years or older.	procedures - Streamlined Authority Code 5461
Clomifene	C6221			Anovulatory infertility	
	C6240			Patients undergoing in-vitro fertilisation	
Clomipramine	C6250			Cataplexy The condition must be associated with narcolepsy.	
	C6251			Obsessive-compulsive disorder	
	C6299			Phobic disorders Patient must be an adult.	
Clonazepam	C6295	P6295		Epilepsy	
	C6296	P6296		Epilepsy The condition must be neurologically proven.	Compliance with Authority Required procedures
	C11683	P11683		For use in patients receiving palliative care	
	C11746	P11746		For use in patients receiving palliative care	
Clonidine		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Clopidogrel		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Clopidogrel with aspirin		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	

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Clostridium botulinum type A toxin - haemagglutinin complex	C5178	P5178		Moderate to severe spasticity of the upper limb Patient must have cerebral palsy. Patient must be aged from 2 to 17 years inclusive. Must be treated by a neurologist; OR Must be treated by an orthopaedic surgeon; OR Must be treated by a paediatrician; OR Must be treated by a rehabilitation specialist; OR Must be treated by a plastic surgeon.	Compliance with Authority Required procedures - Streamlined Authority Code 5178
	C5359	P5359		Dynamic equinus foot deformity The condition must be due to spasticity; AND Patient must have cerebral palsy; AND Patient must be ambulant. Patient must be aged from 2 to 17 years inclusive. Must be treated by a neurologist; OR Must be treated by an orthopaedic surgeon; OR Must be treated by a paediatrician; OR Must be treated by a rehabilitation specialist.	Compliance with Authority Required procedures - Streamlined Authority Code 5359
	C5405	P5405		Blepharospasm or hemifacial spasm Patient must have blepharospasm; OR Patient must have hemifacial spasm. Patient must be aged 18 years or older. Must be treated by a neurologist; OR Must be treated by an ophthalmologist; OR Must be treated by an otolaryngology head and neck surgeon; OR Must be treated by a plastic surgeon.	Compliance with Authority Required procedures - Streamlined Authority Code 5405
	C5406	P5406		Spasmodic torticollis Patient must have spasmodic torticollis; AND The treatment must be as monotherapy; OR The treatment must be as adjunctive therapy to current standard care.	Compliance with Authority Required procedures - Streamlined Authority Code 5406

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a neurologist; OR Must be treated by a plastic surgeon; OR Must be treated by a rehabilitation specialist.	
	C8822	P8822		Dynamic equinus foot deformity The condition must be due to spasticity; AND Patient must have cerebral palsy; AND Patient must be ambulant. Patient must be aged 18 years or older. Must be treated by a neurologist; OR Must be treated by an orthopaedic surgeon; OR Must be treated by a paediatrician; OR Must be treated by a rehabilitation specialist.	Compliance with Authority Required procedures - Streamlined Authority Code 8822
	C8929	P8929		Moderate to severe spasticity of the upper limb Patient must have cerebral palsy. Patient must be aged 18 years or older. Must be treated by a neurologist; OR Must be treated by an orthopaedic surgeon; OR Must be treated by a paediatrician; OR Must be treated by a rehabilitation specialist; OR Must be treated by a plastic surgeon.	Compliance with Authority Required procedures - Streamlined Authority Code 8929
	C9334	P9334		Moderate to severe spasticity of the lower limb following an acute event Must be treated by a neurologist; OR Must be treated by an orthopaedic surgeon; OR Must be treated by a rehabilitation specialist; OR Must be treated by a plastic surgeon; OR Must be treated by a geriatrician. The condition must be moderate to severe spasticity of the lower limb/s following stroke or other acute neurological event, defined as a Modified Ashworth Scale rating of 3 or more; AND The treatment must only be used as second line therapy when standard management has failed; OR	Compliance with Authority Required procedures - Streamlined Authority Code 9334

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				The treatment must only be used as an adjunct to physical therapy; AND The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating of at least 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A); AND Patient must not have established severe contracture in the limb to be treated; AND The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per lower limb in the the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per lower limb each year thereafter. Patient must be aged 18 years or older. Standard management includes physiotherapy and/or oral spasticity agents.	
	C9547	P9547		Moderate to severe spasticity of the upper limb following an acute event The condition must be moderate to severe spasticity of the upper limb/s following an acute event, defined as a Modified Ashworth Scale rating of 3 or more; AND The treatment must only be used as second line therapy when standard management has failed; OR The treatment must only be used as an adjunct to physical therapy; AND The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A); AND The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per upper limb in the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per upper limb each year thereafter; AND Patient must not have established severe contracture in the limb to be treated. Patient must be aged 18 years or older. Must be treated by a neurologist; OR Must be treated by an orthopaedic surgeon; OR Must be treated by a rehabilitation specialist; OR Must be treated by a plastic surgeon; OR Must be treated by a geriatrician.	Compliance with Authority Required procedures - Streamlined Authority Code 9547

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				Standard management includes physiotherapy and/or oral spasticity agents.	
Clozapine	C4998			Schizophrenia Continuing treatment Must be treated by a psychiatrist; OR Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist. Patient must have previously received PBS-subsidised therapy with this drug for this condition; AND Patient must have completed at least 18 weeks therapy; AND Patient must be on a clozapine dosage considered stable by a treating psychiatrist; AND The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals. A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.	Compliance with Authority Required procedures - Streamlined Authority Code 4998
	C5015			Schizophrenia Initial treatment Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient. Patient must be non-responsive to other neuroleptic agents; OR Patient must be intolerant of other neuroleptic agents. Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction. The name of the consulting psychiatrist should be included in the patient's medical records. A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.	Compliance with Authority Required procedures - Streamlined Authority Code 5015
	C9490			Schizophrenia Initial treatment Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.	Compliance with Authority Required procedures - Streamlined

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				Patient must be non-responsive to other neuroleptic agents; OR Patient must be intolerant of other neuroleptic agents. Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction. The name of the consulting psychiatrist should be included in the patient's medical records. A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.	Authority Code 9490
Cobimetinib	C6803	P6803		Unresectable Stage III or Stage IV malignant melanoma Continuing treatment Patient must have previously been issued with an authority prescription for this drug; AND Patient must be receiving PBS-subsidised vemurafenib concomitantly for this condition; AND Patient must have stable or responding disease.	Compliance with Authority Required procedures - Streamlined Authority Code 6803
	C10033	P10033		Unresectable Stage III or Stage IV malignant melanoma Initial treatment Patient must be receiving PBS subsidised vemurafenib concomitantly for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 10033
Codeine	C10764	P10764		Severe pain Continuing PBS treatment after 1 June 2020 Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for: (i) severe disabling pain associated with malignant neoplasia; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or (iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months. Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).	
	C10766	P10766		Severe pain The treatment must be for short term therapy of acute severe pain; AND Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.	
	C10768	P10768		Severe pain Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.	
	C10771	P10771		Severe pain Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months	

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				Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).	
	C10772	P10772		Severe pain Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) severe disabling pain associated with proven malignant neoplasia; or (ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months. Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).	
Codeine with paracetamol	C10764	P10764		Severe pain Continuing PBS treatment after 1 June 2020 Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for: (i) severe disabling pain associated with malignant neoplasia; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or (iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse	

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				practitioner in the past 12 months, but is planned in the next 3 months. Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).	
	C10766	P10766		Severe pain The treatment must be for short term therapy of acute severe pain; AND Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.	
	C10768	P10768		Severe pain Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.	
	C10771	P10771		Severe pain Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).	
	C10772	P10772		Severe pain Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) severe disabling pain associated with proven malignant neoplasia; or (ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months. Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.	

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				Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).	
Colestyramine		P6429		Primary hypercholesterolaemia Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	
Corifollitropin alfa	C5009			Assisted Reproductive Technology The treatment must be for controlled ovarian stimulation; AND Patient must have an antral follicle count of 20 or less; AND Patient must be receiving medical services as described in items 13200, 13201, or 13202 of the Medicare Benefits Schedule; AND Patient must be undergoing a gonadotrophin releasing antagonist cycle.	Compliance with Authority Required procedures - Streamlined Authority Code 5009
Cortisone		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Crizotinib	C13186			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures
	C13233			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				condition; AND The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND Patient must have a WHO performance status of 2 or less. Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be documented in the patient's medical records: (a) evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.	
	C13250			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND Patient must have a WHO performance status of 2 or less; AND Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing; AND Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; OR Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1)	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be documented in the patient's medical records: (a) evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.	
	C13251			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures
Cyproterone		P5532	CN5532	Moderate to severe androgenisation The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation. Patient must be female. Patient must not be pregnant.	Compliance with Authority Required procedures - Streamlined Authority Code 5532
		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
		P14868	CN14868	Moderate to severe androgenisation The condition must be stable for the prescriber to consider the listed maximum	Compliance with Authority Required

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				quantity of this medicine suitable for this patient; AND The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation. Patient must be female. Patient must not be pregnant.	procedures - Streamlined Authority Code 14868
Dabigatran etexilate	C4269	P4269		Prevention of stroke or systemic embolism Patient must have non-valvular atrial fibrillation; AND Patient must have one or more risk factors for developing stroke or systemic embolism. Risk factors for developing stroke or systemic ischaemic embolism are: (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism; (ii) age 75 years or older; (iii) hypertension; (iv) diabetes mellitus; (v) heart failure and/or left ventricular ejection fraction 35% or less.	Compliance with Authority Required procedures - Streamlined Authority Code 4269
	C4369	P4369		Prevention of venous thromboembolism Patient must be undergoing total hip replacement. Patient must require up to 20 days supply to complete a course of treatment.	Compliance with Authority Required procedures - Streamlined Authority Code 4369
	C4381	P4381		Prevention of venous thromboembolism Patient must be undergoing total knee replacement. Patient must require up to 10 days of therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 4381
	C4402	P4402		Prevention of venous thromboembolism Patient must be undergoing total hip replacement. Patient must require up to 30 days supply to complete a course of treatment.	Compliance with Authority Required procedures - Streamlined Authority Code 4402
	C14308	P14308		Prevention of stroke or systemic embolism	Compliance with

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have non-valvular atrial fibrillation; AND Patient must have one or more risk factors for developing stroke or systemic embolism. Risk factors for developing stroke or systemic ischaemic embolism are: (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism; (ii) age 75 years or older; (iii) hypertension; (iv) diabetes mellitus; (v) heart failure and/or left ventricular ejection fraction 35% or less.	Authority Required procedures - Streamlined Authority Code 14078
Dabrafenib	C6013	P6013		Unresectable Stage III or Stage IV malignant melanoma Continuing treatment Patient must have previously been issued with an authority prescription for this drug; AND Patient must have stable or responding disease.	Compliance with Authority Required procedures - Streamlined Authority Code 6013
	C10130	P10130		Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma Continuing treatment Patient must have previously been issued with an authority prescription for trametinib and dabrafenib concomitantly for adjuvant treatment following complete surgical resection; AND Patient must not have experienced disease recurrence; AND Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.	Compliance with Authority Required procedures
	C10148	P10148		Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma Initial treatment The treatment must be adjuvant to complete surgical resection; AND The condition must be positive for a BRAF V600 mutation; AND Patient must have a WHO performance status of 1 or less; AND Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				for this condition; AND Patient must not have received prior PBS-subsidised treatment for this condition; AND The treatment must commence within 12 weeks of complete resection; AND Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.	
	C10157	P10157		Unresectable Stage III or Stage IV malignant melanoma Initial treatment The condition must be positive for a BRAF V600 mutation; AND The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; OR Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal; AND Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage IIIB, IIIC or IIID melanoma; AND Patient must have a WHO performance status of 2 or less.	Compliance with Authority Required procedures - Streamlined Authority Code 10157
Dantrolene	C6359			Chronic spasticity	
Dapagliflozin	C4991	P4991		Diabetes mellitus type 2 The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.	Compliance with Authority Required procedures - Streamlined Authority Code 4991

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.	
	C5629	P5629		Diabetes mellitus type 2 The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:	Compliance with Authority Required procedures - Streamlined Authority Code 5629

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				(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.	
	C7495	P7495		Diabetes mellitus type 2 Continuing treatment The treatment must be in combination with metformin; AND The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 7495
	C7506	P7506		Diabetes mellitus type 2 The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a	Compliance with Authority Required procedures - Streamlined Authority Code 7506

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				glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with a gliptin and an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.	
	C7528	P7528		Diabetes mellitus type 2 Initial treatment The treatment must be in combination with metformin; AND The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a gliptin; OR Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin. The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or	Compliance with Authority Required procedures - Streamlined Authority Code 7528

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				(b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.	
	C13230	P13230		Chronic kidney disease Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug; AND Patient must have an estimated glomerular filtration rate of between 25 to 75 mL/min/1.73 m^2inclusive prior to initiating treatment with this drug; AND Patient must have a urinary albumin to creatinine ratio of between 200 to 5000 mg/g (22.6-565 mg/mmol) inclusive prior to initiating treatment with this drug; AND Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant; AND Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug. Patients with polycystic kidney disease, lupus nephritis or ANCA-associated vasculitis; patients requiring or with a recent history of cytotoxic or immunosuppressive therapy for kidney disease; and patients with an organ transplant are not eligible for treatment with this drug.	Compliance with Authority Required procedures - Streamlined Authority Code 13230
	C14471	P14471		Chronic heart failure Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug; AND Patient must have a documented left ventricular ejection fraction (LVEF) of greater than 40%; AND Patient must have documented evidence of structural changes in the heart on echocardiography that would be expected to cause diastolic dysfunction (e.g. left ventricular hypertrophy); AND	Compliance with Authority Required procedures - Streamlined Authority Code 14471

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have documented evidence of at least one of the following: (i) diastolic dysfunction with high filling pressure on echocardiography, stress echocardiography or cardiac catheterisation; (ii) hospitalisation for heart failure in the 12 months prior to initiating treatment with this drug; (iii) requirement for intravenous diuretic therapy in the 12 months prior to initiating treatment with this drug; (iv) elevated N-terminal pro brain natriuretic peptide (NT-proBNP) levels in the absence of another cause; AND Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.	
	C14859	P14859		Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 14859
	C14905	P14905		Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-	Compliance with Authority Required procedures - Streamlined Authority Code 14905

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				like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with a gliptin and an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.	
	C14949	P14949		Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 14949

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				Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.	
	C14974	P14974		Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels	Compliance with Authority Required procedures - Streamlined Authority Code 14974

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				in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.	
	C15047	P15047		Chronic heart failure Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug; AND Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%; AND The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15047
	C15051	P15051		Chronic heart failure The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND	Compliance with Authority Required procedures - Streamlined

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug; AND Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%; AND The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.	Authority Code 15051
Dapagliflozin with metformin	C5631	P5631		Diabetes mellitus type 2 Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels	Compliance with Authority Required procedures - Streamlined Authority Code 5631

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.	
	C5657	P5657		Diabetes mellitus type 2 The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or	Compliance with Authority Required procedures - Streamlined Authority Code 5657

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.	
	C5739	P5739		Diabetes mellitus type 2 Continuing treatment Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and dapagliflozin.	Compliance with Authority Required procedures - Streamlined Authority Code 5739
	C5798	P5798		Diabetes mellitus type 2 The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like	Compliance with Authority Required procedures - Streamlined Authority Code 5798

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.	
	C7492	P7492		Diabetes mellitus type 2 Continuing treatment The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 7492
	C7498	P7498		Diabetes mellitus type 2 Initial treatment The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and a gliptin for this condition; OR Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin. The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic	Compliance with Authority Required procedures - Streamlined Authority Code 7498

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.	
	C14878	P14878		Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with	Compliance with Authority Required procedures - Streamlined Authority Code 14878

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.	
	C14881	P14881		Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 14881
	C14924	P14924		Diabetes mellitus type 2	Compliance with

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.	Authority Required procedures - Streamlined Authority Code 14924
	C14987	P14987		Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and dapagliflozin.	Compliance with Authority Required procedures - Streamlined Authority Code 14987
Daratumumab	C12691	P12691		Relapsed and/or refractory multiple myeloma Continuing treatment of second-line drug therapy from week 25 until disease progression (administered every 4 weeks) Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	
	C12842	P12842		Relapsed and/or refractory multiple myeloma Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have been on treatment with this drug in the subcutaneous form for this condition prior to 1 November 2021; AND Patient must have met all initial treatment PBS-eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are: (i) the condition was confirmed by histological diagnosis, (ii) the treatment is/was being used as part of triple combination therapy with bortezomib and dexamethasone, (iii) the condition progressed (see definition of progressive disease below) after one prior therapy, but not after more than two prior lines of therapies (i.e. this drug was commenced as second-line treatment), (iv) the treatment was/is not to be used in combination with another PBS-subsidised drug indicated for this condition outside of the intended combination where stated, and (v) the patient had never been treated with this drug; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records. Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records: (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records. A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner. A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.	
	C12844			Relapsed and/or refractory multiple myeloma Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 January 2021; AND Patient must have met all initial treatment PBS-eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are: (i) the condition was confirmed by histological diagnosis, (ii) the treatment is/was being used as part of triple combination therapy with bortezomib and dexamethasone, (iii) the condition progressed (see definition of progressive disease below) after one prior therapy, but not after more than two prior lines of therapies (i.e. this drug was commenced as second-line treatment), (iv) the treatment was/is not to be used in combination with another PBS-subsidised drug indicated for this condition outside of the intended combination where stated, and (v) the patient had never been treated with this drug; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records. Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records: (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be	

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				documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records. A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner. A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.	
	C12845	P12845		Relapsed and/or refractory multiple myeloma Continuing treatment of second-line drug therapy for weeks 10 to 24 (administered every 3 weeks) Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with bortezomib and dexamethasone; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	
	C13752	P13752		Relapsed and/or refractory multiple myeloma Initial treatment as second-line drug therapy for weeks 1 to 9 (administered once weekly) The condition must be confirmed by a histological diagnosis; AND The treatment must be in combination with bortezomib and dexamethasone; AND Patient must have progressive disease after only one prior therapy (i.e. use must be as second-line drug therapy; use as third-line drug therapy or beyond is not PBS-subsidised). Patient must be undergoing treatment with this drug in one of the following situations: (i) for the first time, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), (ii) changing the drug's form (intravenous/subcutaneous) within the first 9 weeks of treatment for the same PBS indication. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records. Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records: (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records. A line of therapy is defined as 1 or more cycles of a planned treatment program. This	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner. A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.	
	C13774	P13774		Newly diagnosed systemic light chain amyloidosis Continuing treatment from week 25 onwards (administered once every four weeks) Patient must have previously received PBS-subsidised treatment with this drug for this condition. Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist); AND Patient must be undergoing continuing treatment that does not extend treatment duration beyond whichever comes first: (i) disease progression, (ii) 96 cumulative weeks from the first administered dose, once in a lifetime.	Compliance with Authority Required procedures
	C13944	P13944		Newly diagnosed systemic light chain amyloidosis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must be continuing treatment with this drug that was commenced as non-PBS-subsidised supply prior to 1 January 2023; AND The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis; AND The condition must have been, prior to the first dose of the non-PBS-subsidised supply, untreated with drug therapy, including this drug, irrespective of whether the diagnosis had been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis); AND Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time non-PBS supply was initiated.	Compliance with Written Authority Required procedures

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				Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist); AND Patient must be undergoing concomitant treatment limited to each of: (i) bortezomib, (ii) cyclophosphamide, (iii) dexamethasone, at certain weeks of treatment as outlined in the drug's approved Product Information; AND Patient must be undergoing continuing treatment that does not extend treatment duration beyond whichever comes first: (i) disease progression, (ii) 96 cumulative weeks from the first administered dose, once in a lifetime. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include: Details of the histological evidence supporting the diagnosis of systemic light chain amyloidosis, limited to: (i) the name of pathologist/pathology provider, (ii) the site of biopsy If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Determine an appropriate number of repeat prescriptions for this authority application in line with either: (i) Where the patient has received less than 10 non-PBS-subsidised doses, prescribe a number of repeat prescriptions up to the balance of: 15 doses less the number of non-PBS-subsidised doses; or (ii) Where the patient has received at least 10 non-PBS-subsidised doses, prescribe no more than 5 repeat prescriptions.	
	C14015	P14015		Newly diagnosed systemic light chain amyloidosis Initial treatment from week 0 to week 24 The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis; AND The condition must be untreated with drug therapy, including this drug, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis changes between	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				multiple myeloma/amyloidosis); AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation. Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist); AND Patient must be undergoing concomitant treatment limited to each of: (i) bortezomib, (ii) cyclophosphamide, (iii) dexamethasone, at certain weeks of treatment as outlined in the drug's approved Product Information. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include: Details of the histological evidence supporting the diagnosis of systemic light chain amyloidosis, limited to: (i) the name of pathologist/pathology provider, (ii) the site of biopsy If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
Darbepoetin alfa	C6294			Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6294
	C9688			Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9688
Darolutamide	C12895			Castration resistant non-metastatic carcinoma of the prostate The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition;	Compliance with Authority Required

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				AND The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation. Patient must be undergoing concurrent treatment with androgen deprivation therapy. Prescribing instructions: Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application. The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.	procedures
	C14034			Metastatic castration sensitive carcinoma of the prostate The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy; AND Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				treatment cessation; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug. Patient must be undergoing concurrent androgen deprivation therapy.	
Darunavir	C4313			Human immunodeficiency virus (HIV) infection The treatment must be in addition to optimised background therapy; AND The treatment must be in combination with other antiretroviral agents; AND The treatment must be co-administered with 100 mg ritonavir; AND Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen; AND Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.	Compliance with Authority Required procedures - Streamlined Authority Code 4313
	C5094			Human immunodeficiency virus (HIV) infection The treatment must be in addition to optimised background therapy; AND The treatment must be in combination with other antiretroviral agents; AND The treatment must be co-administered with 100 mg ritonavir twice daily; AND Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.	Compliance with Authority Required procedures - Streamlined Authority Code 5094
Darunavir with cobicistat	C6377			Human immunodeficiency virus (HIV) infection The treatment must be in addition to optimised background therapy; AND The treatment must be in combination with other antiretroviral agents; AND The treatment must not be in combination with ritonavir; AND Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen. Virological failure is defined as a viral load greater than 400 copies per mL on two	Compliance with Authority Required procedures - Streamlined Authority Code 6377

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.	
	C6413			Human immunodeficiency virus (HIV) infection Initial treatment Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents; AND The treatment must not be in combination with ritonavir.	Compliance with Authority Required procedures - Streamlined Authority Code 6413
	C6428			Human immunodeficiency virus (HIV) infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents; AND The treatment must not be in combination with ritonavir.	Compliance with Authority Required procedures - Streamlined Authority Code 6428
Darunavir with cobicistat, emtricitabine and tenofovir alafenamide	C10317			HIV infection Continuing treatment Must be treated by a medical practitioner or an authorised nurse practitioner in consultation with a medical practitioner. Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must not be in combination with ritonavir.	Compliance with Authority Required procedures - Streamlined Authority Code 10317
	C10324			HIV infection Initial treatment Must be treated by a medical practitioner or an authorised nurse practitioner in consultation with a medical practitioner. Patient must be antiretroviral treatment naive; OR Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen; AND The treatment must not be in combination with ritonavir. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.	Compliance with Authority Required procedures - Streamlined Authority Code 10324

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Dasatinib	C9367	P9367		Acute lymphoblastic leukaemia Initial treatment Patient must be newly diagnosed; AND The condition must be expressing the Philadelphia chromosome; OR The condition must have the transcript BCR-ABL; AND The treatment must be for induction and consolidation therapy; AND The treatment must be in combination with chemotherapy or corticosteroids; AND Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and (c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided).	Compliance with Written Authority Required procedures
	C9468	P9468		Acute lymphoblastic leukaemia Initial treatment The condition must be expressing the Philadelphia chromosome; OR The condition must have the transcript BCR-ABL; AND Patient must have failed treatment with chemotherapy; AND Patient must have failed treatment with imatinib; AND Patient must have failed an allogeneic haemopoeitic stem cell transplantation if applicable. Failure of treatment is defined as either: (i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib;	Compliance with Written Authority Required procedures

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				(ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib; (iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation. Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells expressing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and (c) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.	
	C9469	P9469		Acute lymphoblastic leukaemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with imatinib as a first-line therapy for this condition; AND The condition must be expressing the Philadelphia chromosome; OR The condition must have the transcript BCR-ABL; AND The treatment must be for maintenance of first complete remission; AND The treatment must be in combination with chemotherapy or corticosteroids. Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting.	Compliance with Authority Required procedures

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	C9549	P9549		Acute lymphoblastic leukaemia Continuing treatment The condition must be expressing the Philadelphia chromosome; OR The condition must have the transcript BCR-ABL; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition as second-line therapy following treatment with imatinib; AND The condition must not have progressed.	Compliance with Authority Required procedures
	C12522	P12522		Chronic Myeloid Leukaemia (CML) Continuing treatment - third-line therapy Patient must have received initial PBS-subsidised treatment with this drug as a third-line therapy for this condition; AND Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals; AND The treatment must be the sole PBS-subsidised therapy for this condition. A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 12522
	C12524	P12524		Chronic Myeloid Leukaemia (CML) Initial treatment - second-line therapy The condition must be in the chronic phase; OR The condition must be in the accelerated phase; OR The condition must be in the blast phase; AND Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting; AND Patient must have failed an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition; OR Patient must have failed an adequate trial of PBS-subsidised first-line treatment with nilotinib for this condition; OR	Compliance with Authority Required procedures

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				Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with nilotinib for this condition; AND The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND The treatment must be the sole PBS-subsidised therapy for this condition. Failure of an adequate trial of imatinib or nilotinib is defined as: (i) Lack of response to initial imatinib or nilotinib therapy, defined as either: - failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or nilotinib for patients initially treated in chronic phase; or - failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or - failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or nilotinib; OR (ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or nilotinib therapy; OR (iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or nilotinib therapy; OR (iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or nilotinib for any phase of chronic myeloid leukaemia. Accelerated phase is defined by the presence of 1 or more of the following: (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or (3) Peripheral basophils greater than or equal to 20%; or (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left	

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				costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); Blast crisis is defined as either: (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or (2) Extramedullary involvement other than spleen and liver; OR (v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia. Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals. A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records. Pathology report(s) confirming a loss of response to imatinib or nilotinib, from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement must be documented in the patient's medical records.	
	C12530	P12530		Chronic Myeloid Leukaemia (CML) Continuing treatment - second-line therapy Patient must have received initial PBS-subsidised treatment with this drug as a second-line therapy for this condition; OR Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with nilotinib for this condition; AND Patient must have demonstrated a major cytogenic response of less than 35%	Compliance with Authority Required procedures - Streamlined Authority Code 12530

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				Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals; AND The treatment must be the sole PBS-subsidised therapy for this condition. A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.	
	C12561	P12561		Chronic Myeloid Leukaemia (CML) Initial treatment - third-line therapy The condition must be in the chronic phase; OR The condition must be in the accelerated phase; OR The condition must be in the blast phase; AND Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting; OR Patient must not have failed PBS-subsidised treatment with this drug for this condition in the second-line setting; AND Patient must have documented failure with an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition; AND Patient must have failed an adequate trial of PBS-subsidised second-line treatment with nilotinib for this condition; AND The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND The treatment must be the sole PBS-subsidised therapy for this condition. Failure of an adequate trial of nilotinib is defined as: (i) Lack of response to second line nilotinib therapy, defined as either: - failure to achieve a haematological response after a minimum of 3 months therapy with nilotinib for patients initially treated in chronic phase; or - failure to achieve any cytogenetic response after a minimum of 6 months therapy with nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive	Compliance with Authority Required procedures

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				cells; or - failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with nilotinib; OR ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing nilotinib therapy; OR (iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing nilotinib therapy; OR (iv) Development of accelerated phase or blast crisis in a patient previously prescribed nilotinib for any phase of chronic myeloid leukaemia. Accelerated phase is defined by the presence of 1 or more of the following: (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or (3) Peripheral basophils greater than or equal to 20%; or (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR Blast crisis is defined as either: (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or (2) Extramedullary involvement other than spleen and liver; OR (v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia. Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1%	

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				within 18 months and thereafter at 12 monthly intervals. A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records. Pathology report(s) confirming a loss of response to imatinib and nilotinib, from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement must be documented in the patient's medical records.	
	C12565	P12565		Chronic Myeloid Leukaemia (CML) Continuing treatment - first-line therapy The condition must be in the chronic phase; AND Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition; OR Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with imatinib for this condition; OR Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with nilotinib for this condition; AND Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals; AND The treatment must be the sole PBS-subsidised therapy for this condition. A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 12565
	C12570	P12570		Chronic Myeloid Leukaemia (CML) Initial treatment - first-line therapy Patient must have a primary diagnosis of chronic myeloid leukaemia; AND	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must be in the chronic phase; AND The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; OR Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition; OR Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first-line therapy for this condition; AND The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND The treatment must be the sole PBS-subsidised therapy for this condition. Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved. Patients should be commenced on a dose of dasatinib of 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to dasatinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter. A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records. The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.	

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Decitabine with cedazuridine	C13165	P13165		Chronic Myelomonocytic Leukaemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease. Up to 6 cycles will be authorised.	Compliance with Authority Required procedures
	C13205	P13205		Chronic Myelomonocytic Leukaemia Initial treatment The condition must be chronic myelomonocytic leukaemia confirmed through a bone marrow biopsy report and full blood examination report; AND The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder. No more than 3 cycles will be authorised under this restriction in a patient's lifetime. The first authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has chronic myelomonocytic leukaemia; and (b) details (date, unique identifying number/code or provider number) of the full blood examination report from an Approved Pathology Authority All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following reports must be documented in the patient's medical records: (a) bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia; and (b) full blood examination report	Compliance with Written Authority Required procedures
	C13241	P13241		Acute Myeloid Leukaemia	Compliance with

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Initial treatment The condition must be acute myeloid leukaemia confirmed through a bone marrow biopsy report and full blood examination; AND The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification. The following reports must be documented in the patient's medical records: (a) bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and (b) full blood examination report.	Authority Required procedures
	C13257	P13257		Myelodysplastic syndrome Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease. Up to 6 cycles will be authorised.	Compliance with Authority Required procedures
	C13258	P13258		Acute Myeloid Leukaemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease.	Compliance with Authority Required procedures - Streamlined Authority Code 13258
	C13267	P13267		Myelodysplastic syndrome Initial treatment The condition must be myelodysplastic syndrome confirmed through a bone marrow biopsy report and full blood examination; AND The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS); AND The condition must have up to 20% marrow blasts according to World Health Organisation (WHO) Classification. Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				IPSS, achieved with the possible combinations: (a) 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR (b) 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR (c) 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR (d) 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR (e) Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias. Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations: (a) 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR (b) 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias. The following information must be provided by the prescriber at the time of application: (a) The patient's International Prognostic Scoring System (IPSS) score. The following reports must be documented in the patient's medical records: (a) bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and (b) full blood examination report; and (c) pathology report detailing the cytogenetics demonstrating intermediate-2 or high-risk disease according to the International Prognostic Scoring System (IPSS). No more than 3 cycles will be authorised under this restriction in a patient's lifetime.	
Deferasirox	C7374	P7374		Chronic iron overload Initial treatment Patient must not be transfusion dependent; AND The condition must be thalassaemia.	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C7375	P7375		Chronic iron overload Initial treatment Patient must be transfusion dependent; AND Patient must not have a malignant disorder of erythropoiesis.	Compliance with Authority Required procedures
	C7385	P7385		Chronic iron overload Initial treatment Patient must be red blood cell transfusion dependent; AND Patient must have a serum ferritin level of greater than 1000 microgram/L; AND Patient must have a malignant disorder of haemopoiesis; AND Patient must have a median life expectancy exceeding five years.	Compliance with Authority Required procedures
	C8326	P8326		Chronic iron overload Continuing treatment Patient must be red blood cell transfusion dependent; AND Patient must have a malignant disorder of haemopoieisis; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 8326
	C8328	P8328		Chronic iron overload Continuing treatment Patient must be transfusion dependent; AND Patient must not have a malignant disorder of erythropoiesis; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 8328
	C8329	P8329		Chronic iron overload Continuing treatment Patient must not be transfusion dependent; AND The condition must be thalassaemia; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 8329

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C9222	P9222		Chronic iron overload Continuing treatment Patient must not be transfusion dependent; AND The condition must be thalassaemia; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 9222
	C9258	P9258		Chronic iron overload Continuing treatment Patient must be red blood cell transfusion dependent; AND Patient must have a malignant disorder of haemopoieisis; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 9258
	C9302	P9302		Chronic iron overload Continuing treatment Patient must be transfusion dependent; AND Patient must not have a malignant disorder of erythropoiesis; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 9302
Deferiprone	C6403			Iron overload Patient must have thalassaemia major; AND Patient must be one in whom desferrioxamine therapy has proven ineffective.	Compliance with Authority Required procedures - Streamlined Authority Code 6403
	C6448			Iron overload Patient must have thalassaemia major; AND Patient must be unable to take desferrioxamine therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 6448
	C9228			Iron overload Patient must have thalassaemia major; AND	Compliance with Authority Required procedures - Streamlined

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				Patient must be one in whom desferrioxamine therapy has proven ineffective.	Authority Code 9228
	C9286			Iron overload Patient must have thalassaemia major; AND Patient must be unable to take desferrioxamine therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 9286
	C9590			Iron overload Patient must have thalassaemia major; AND Patient must be one in whom desferrioxamine therapy has proven ineffective.	Compliance with Authority Required procedures - Streamlined Authority Code 9590
	C9623			Iron overload Patient must have thalassaemia major; AND Patient must be unable to take desferrioxamine therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 9623
Degarelix	C6952			Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate	
	C6976			Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate	
Denosumab	C4150			Bone metastases The condition must be due to castration-resistant prostate cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 4150
	C4158			Bone metastases The condition must be due to breast cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 4158
	C4504			Giant cell tumour of bone Patient must be one in whom surgical resection is not feasible; OR	Compliance with Authority Required

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				Patient must be one in whom surgical resection is possible but surgery would result in significant morbidity. Patient must be an adult; OR Patient must be a skeletally mature adolescent.	procedures - Streamlined Authority Code 4504
	C6524			Established osteoporosis Patient must have fracture due to minimal trauma; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.	Compliance with Authority Required procedures - Streamlined Authority Code 6524
	C6548			Osteoporosis Patient must be aged 70 years or older. Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 6548
Desferrioxamine	C6394			Disorders of erythropoiesis The condition must be associated with treatment-related chronic iron overload.	Compliance with Authority Required procedures - Streamlined Authority Code 6394
	C9696			Disorders of erythropoiesis The condition must be associated with treatment-related chronic iron overload.	Compliance with Authority Required procedures - Streamlined

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					Authority Code 9696
Desmopressin	C5226	P5226		Primary nocturnal enuresis Patient must be 6 years of age or older. Patient must be one in whom an enuresis alarm is contraindicated. The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated	Compliance with Authority Required procedures - Streamlined Authority Code 5226
	C5266	P5266		Cranial diabetes insipidus	Compliance with Authority Required procedures - Streamlined Authority Code 5266
	C5267	P5267		Primary nocturnal enuresis Patient must be 6 years of age or older. Patient must be one in whom an enuresis alarm is contraindicated. The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated	Compliance with Authority Required procedures - Streamlined Authority Code 5267
	C5295	P5295		Primary nocturnal enuresis Patient must be 6 years of age or older. Patient must be one in whom an enuresis alarm is contraindicated. The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated	Compliance with Authority Required procedures - Streamlined Authority Code 5295
	C5342	P5342		Primary nocturnal enuresis Patient must be 6 years of age or older. Patient must be refractory to an enuresis alarm.	Compliance with Authority Required procedures - Streamlined Authority Code 5342
	C5412	P5412		Primary nocturnal enuresis Patient must be 6 years of age or older. Patient must be refractory to an enuresis alarm.	Compliance with Authority Required procedures - Streamlined Authority Code 5412

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C5413	P5413		Primary nocturnal enuresis Patient must be 6 years of age or older. Patient must be refractory to an enuresis alarm.	Compliance with Authority Required procedures - Streamlined Authority Code 5413
	C14842	P14842		Primary nocturnal enuresis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must be 6 years of age or older. Patient must be one in whom an enuresis alarm is contraindicated. The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated No more than twice the maximum quantity will be authorised.	Compliance with Authority Required procedures - Streamlined Authority Code 14842
	C14945	P14945		Primary nocturnal enuresis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must be 6 years of age or older. Patient must be refractory to an enuresis alarm. No increase in the maximum quantity or number of units may be authorised.	Compliance with Authority Required procedures - Streamlined Authority Code 14945
	C14972	P14972		Primary nocturnal enuresis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must be 6 years of age or older. Patient must be refractory to an enuresis alarm. No more than twice the maximum quantity will be authorised.	Compliance with Authority Required procedures - Streamlined Authority Code 14972
	C15012	P15012		Cranial diabetes insipidus The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	Compliance with Authority Required procedures - Streamlined Authority Code 15012

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C15025	P15025		Primary nocturnal enuresis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must be 6 years of age or older. Patient must be one in whom an enuresis alarm is contraindicated. The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated No increase in the maximum quantity or number of units may be authorised.	Compliance with Authority Required procedures - Streamlined Authority Code 15025
Desvenlafaxine	C5650			Major depressive disorders	
Deucravacitinib	C14384			Severe chronic plaque psoriasis Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; OR Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; OR Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; AND The condition must have caused significant interference with quality of life; AND Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin, (iii) apremilast. Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist; OR Must be treated by a general practitioner who has been directed to continue treatment (not initiate treatment) by one of the above practitioner types. Patient must be at least 18 years of age.	Compliance with Authority Required procedures - Streamlined Authority Code 14384
Dexamethasone	C7566	P7566		Non-infectious posterior segment uveitis Must be treated by an ophthalmologist or in consultation with an ophthalmologist. Patient must have documented visual impairment defined as a best corrected visual acuity score of approximate Snellen equivalent 6/12 or worse in the eye proposed for treatment, secondary to vitreous haze or macular oedema; AND Patient must have unilateral, asymmetric or bilateral flare-up where systemic	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				treatment or further intensification of systemic treatment is not clinically indicated.	
		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
	C13336	P13336		Central retinal vein occlusion with macular oedema Continuing treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 13336
	C13341	P13341		Diabetic macular oedema (DMO) Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Patient must have visual impairment due to diabetic macular oedema; AND Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment; AND The condition must be diagnosed by optical coherence tomography; OR The condition must be diagnosed by fluorescein angiography; AND Patient must have had a cataract removed in the treated eye; OR Patient must be scheduled for cataract surgery in the treated eye; AND Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR Patient must be unsuitable for treatment with VEGF inhibitors; OR Patient must have failed prior treatment with VEGF inhibitors; AND The treatment must be as monotherapy; OR The treatment must be in combination with laser photocoagulation; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. If the application is submitted through HPOS form upload or mail, it must include: (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.	
	C13387	P13387		Branch retinal vein occlusion with macular oedema Continuing treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 13387
	C13423	P13423		Central retinal vein occlusion with macular oedema Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO); AND Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment; AND The condition must be diagnosed by optical coherence tomography; OR The condition must be diagnosed by fluorescein angiography; AND Patient must have a contraindication to vascular endothelial growth factor (VEGF)	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				inhibitors; OR Patient must have failed prior treatment with VEGF inhibitors; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. If the application is submitted through HPOS form upload or mail, it must include: (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.	
	C13428	P13428		Diabetic macular oedema (DMO) Continuing treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Patient must have had a cataract removed in the treated eye; OR Patient must be scheduled for cataract surgery in the treated eye; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND The treatment must be as monotherapy; OR The treatment must be in combination with laser photocoagulation; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 13428
	C13429	P13429		Branch retinal vein occlusion with macular oedema Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Patient must have visual impairment due to macular oedema secondary to branched	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				retinal vein occlusion (BRVO); AND Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment; AND The condition must be diagnosed by optical coherence tomography; OR The condition must be diagnosed by fluorescein angiography; AND Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR Patient must have failed prior treatment with VEGF inhibitors; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. If the application is submitted through HPOS form upload or mail, it must include: (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.	
Dexamfetamine	C6226			Attention deficit hyperactivity disorder Treatment must be in accordance with the law of the relevant State or Territory.	Compliance with Authority Required procedures
	C6227			Narcolepsy	Compliance with Authority Required procedures
Diazepam	C4244			Chronic spasticity	Compliance with Authority Required

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				Patient must be under 18 years of age.	procedures
		P6176	CN6176	Anxiety Patient must be receiving palliative care.	Compliance with Authority Required procedures
Dicloxacillin	C5268			Serious staphylococcal infection	
	C5415	P5415		Serious staphylococcal infection	
	C6188	P6188		Osteomyelitis	Compliance with Authority Required procedures - Streamlined Authority Code 6188
Dimethyl fumarate	C10139			Multiple sclerosis Continuing treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not show continuing progression of disability while on treatment with this drug. Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 10139
	C10140			Multiple sclerosis Initial treatment	Compliance with Authority Required

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support). Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.	procedures - Streamlined Authority Code 10140
Diroximel fumarate	C13034			Multiple sclerosis Continuing treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not show continuing progression of disability while on treatment with this drug. Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 13034
	C13072			Multiple sclerosis	Compliance with

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Initial treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support). Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.	Authority Required procedures - Streamlined Authority Code 13072
Dolutegravir	C4454			HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512			HIV infection Initial Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Dolutegravir with abacavir and lamivudine	C9981			HIV infection Initial treatment Patient must be antiretroviral treatment naive.	Compliance with Authority Required procedures - Streamlined Authority Code 9981
	C10116			HIV infection Continuing treatment	Compliance with Authority Required procedures - Streamlined

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				Patient must have previously received PBS-subsidised therapy for HIV infection.	Authority Code 10116
Dolutegravir with lamivudine	C9987			HIV infection Initial treatment Patient must be antiretroviral treatment naive; AND Patient must not have suspected resistance to either antiretroviral component.	Compliance with Authority Required procedures - Streamlined Authority Code 9987
	C11066			HIV infection Continuing or change of treatment Patient must have previously received PBS-subsidised therapy for HIV infection.	Compliance with Authority Required procedures - Streamlined Authority Code 11066
Dolutegravir with rilpivirine	C8214			HIV infection Initial treatment Patient must be virologically suppressed on a stable antiretroviral regimen for at least 6 months; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 8214
	C8226			HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 8226
Donepezil	C13938			Mild to moderately severe Alzheimer disease Continuing Patient must have received six months of sole PBS-subsidised initial therapy with this drug; AND Patient must demonstrate a clinically meaningful response to the initial treatment; AND The treatment must be the sole PBS-subsidised therapy for this condition. Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile	Compliance with Authority Required procedures - Streamlined Authority Code 13938

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				benefit. Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use. Re-assessments for a clinically meaningful response are to be undertaken and documented every six months. Clinically meaningful response to treatment is demonstrated in the following areas: Patient's quality of life including but not limited to level of independence and happiness; Patient's cognitive function including but not limited to memory, recognition and interest in environment; Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.	
	C13940			Mild to moderately severe Alzheimer disease Initial Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs. Patients who qualify under this criterion are from 1 or more of the following groups: (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background; (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate; (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(4) Intellectual (developmental or acquired) disability, eg Down's syndrome; (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test; (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment. Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.	
	C13941			Mild to moderately severe Alzheimer disease Initial Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified. Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.	Compliance with Authority Required procedures
Dornase alfa	C5634			Cystic fibrosis Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy. Patient must be less than 5 years of age.	Compliance with Authority Required procedures - Streamlined Authority Code 5634

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.	
	C5635			Cystic fibrosis Continuing treatment Patient must have initiated treatment with dornase alfa at an age of less than 5 years; AND Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Patient must be 5 years of age or older. Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.	Compliance with Authority Required procedures - Streamlined Authority Code 5635
	C5740			Cystic fibrosis Patient must be 5 years of age or older. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease. Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily. To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:	Compliance with Authority Required procedures - Streamlined Authority Code 5740

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient. Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.	
	C9591			Cystic fibrosis Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy. Patient must be less than 5 years of age. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.	Compliance with Authority Required procedures - Streamlined Authority Code 9591
	C9592			Cystic fibrosis Continuing treatment Patient must have initiated treatment with dornase alfa at an age of less than 5 years;	Compliance with Authority Required procedures - Streamlined

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				AND Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Patient must be 5 years of age or older. Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.	Authority Code 9592
	C9624			Cystic fibrosis Patient must be 5 years of age or older. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease. Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily. To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment: (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient. Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.	Compliance with Authority Required procedures - Streamlined Authority Code 9624
Dorzolamide with timolol	C4343			Elevated intra-ocular pressure The condition must have been inadequately controlled with monotherapy; AND Patient must have open-angle glaucoma; OR Patient must have ocular hypertension.	

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C5038			Elevated intra-ocular pressure The condition must have been inadequately controlled with monotherapy; AND Patient must have open-angle glaucoma; OR Patient must have ocular hypertension.	
Doxorubicin - pegylated liposomal		P6234	CN6234	Kaposi sarcoma The condition must be AIDS-related; AND Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND The condition must include extensive mucocutaneous involvement.	Compliance with Authority Required procedures - Streamlined Authority Code 6234
		P6274	CN6274	Kaposi sarcoma The condition must be AIDS-related; AND Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND The condition must include extensive visceral involvement.	Compliance with Authority Required procedures - Streamlined Authority Code 6274
		P9223	CN9223	Kaposi sarcoma The condition must be AIDS-related; AND Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND The condition must include extensive visceral involvement.	Compliance with Authority Required procedures - Streamlined Authority Code 9223
		P9287	CN9287	Kaposi sarcoma The condition must be AIDS-related; AND Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND The condition must include extensive mucocutaneous involvement.	Compliance with Authority Required procedures - Streamlined Authority Code 9287
Doxycycline	C4475			Chronic bronchitis Patient must be aged 8 years or older.	
		P4485		Urethritis	
		P4514		Pelvic inflammatory disease	
	C4529			Severe acne	
	C4539			Bronchiectasis	

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				Patient must be aged 8 years or older.	
		P6200		Severe acne	
Dulaglutide	C5469			Diabetes mellitus type 2 The treatment must be in combination with insulin; AND The treatment must be in combination with metformin unless contraindicated or not tolerated; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 5469

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C5478			Diabetes mellitus type 2 The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 5478
	C7645			Diabetes mellitus type 2 The treatment must be in combination with metformin; AND Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR Patient must not have tolerated a combination of metformin and a sulfonylurea; AND	Compliance with Authority Required procedures - Streamlined Authority Code 7645

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with metformin; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with metformin. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.	
Duloxetine	C5650			Major depressive disorders	
Dupilumab	C11374			Chronic severe atopic dermatitis Continuing or resuming treatment of the whole body Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the whole body; AND Patient must have achieved an adequate response within the first 16 weeks of treatment; OR Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				the second or subsequent Continuing treatment authority application; OR Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application; AND The treatment must be the sole PBS-subsidised biological medicine for this PBS indication. Must be treated by a dermatologist; OR Must be treated by a clinical immunologist. For the purposes of this restriction, an adequate response to treatment is defined as: (a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and (b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above. State each of the current EASI and DLQI scores for this authority application.	
	C11377			Chronic severe atopic dermatitis Continuing or resuming treatment of the face and/or hands Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the face/hands; AND Patient must have achieved an adequate response within the first 16 weeks of treatment; OR Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is the second or subsequent Continuing treatment authority application; OR Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application; AND The treatment must be the sole PBS-subsidised biological medicine for this PBS indication. Must be treated by a dermatologist; OR Must be treated by a clinical immunologist. For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as: (a) (i) A rating of either mild (1) to none (0) on at least 3 of the assessments of erythema, oedema/papulation, excoriation and lichenification mentioned in the Eczema Area and Severity Index (EASI); or (ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and (b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above. Document each qualifying response measure in the patient's medical records for PBS compliance auditing purposes	
	C12497			Chronic severe atopic dermatitis Initial treatment of the whole body Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands; AND The treatment must be the sole PBS-subsidised biological medicine for this PBS indication; AND Patient must not have experienced an inadequate response to this biological medicine in this PBS indication. Must be treated by a dermatologist; OR Must be treated by a clinical immunologist. Patient must be 12 years of age or older. State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application. Acceptable scores can be: (a) current scores; or (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication. The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records. Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records.	
	C12507			Chronic severe atopic dermatitis Initial treatment of the face and/or hands The condition must have at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days;	Compliance with Written Authority Required procedures

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				OR The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands; AND The treatment must be the sole PBS-subsidised biological medicine for this PBS indication; AND Patient must not have experienced an inadequate response to this biological medicine in this PBS indication. Must be treated by a dermatologist; OR Must be treated by a clinical immunologist. Patient must be 12 years of age or older. State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for: (i) erythema, (ii) oedema/papulation, (iii) excoriation, (iv) lichenification Acceptable scores can be: (a) current scores; or (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication. State the percentage face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores. The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under	

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records. Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records.	
Durvalumab	C10126			Unresectable Stage III non-small cell lung cancer Initial treatment Patient must have received platinum based chemoradiation therapy; AND The condition must not have progressed following platinum based chemoradiation therapy; AND Patient must have a WHO performance status of 0 or 1; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 10126
	C10206			Extensive-stage small cell lung cancer Initial treatment The condition must be previously untreated; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be in combination with etoposide and a platinum-based antineoplastic drug.	Compliance with Authority Required procedures - Streamlined Authority Code 10206
	C10509			Extensive-stage small cell lung cancer Continuing treatment - 4 weekly treatment regimen The treatment must be as monotherapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 10509
	C12271			Unresectable Stage III non-small cell lung cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for	Compliance with Authority Required procedures - Streamlined

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				this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The treatment must not exceed 12 months in total for this condition under the initial and continuing restriction combined; AND The treatment must be once in a lifetime with this drug for this condition.	Authority Code 12271
	C14708			Locally advanced, metastatic or recurrent biliary tract cancer (intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer) Patient must have either of the following at treatment initiation: (i) locally advanced biliary tract cancer that is untreated with systemic anti-cancer therapy in the unresectable setting, (ii) metastatic biliary tract cancer that is untreated with systemic anti-cancer therapy in the metastatic setting. Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. The treatment must be/have been initiated with both: (i) gemcitabine, (ii) cisplatin (refer to Product Information of gemcitabine and cisplatin for dosing information); AND Patient must not have developed disease progression while being treated with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 14708
Dutasteride	C6202	P6202		Benign prostatic hyperplasia Patient must have lower urinary tract symptoms; AND Patient must have moderate to severe benign prostatic hyperplasia; AND The treatment must be in combination with an alpha-antagonist.	Compliance with Authority Required procedures - Streamlined Authority Code 6202
	C15018	P15018		Benign prostatic hyperplasia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have lower urinary tract symptoms; AND Patient must have moderate to severe benign prostatic hyperplasia; AND	Compliance with Authority Required procedures - Streamlined Authority Code 15018

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				The treatment must be in combination with an alpha-antagonist.	
Dutasteride with tamsulosin	C6189	P6189		Benign prostatic hyperplasia Patient must have lower urinary tract symptoms; AND Patient must have moderate to severe benign prostatic hyperplasia.	Compliance with Authority Required procedures - Streamlined Authority Code 6189
	C15004	P15004		Benign prostatic hyperplasia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have lower urinary tract symptoms; AND Patient must have moderate to severe benign prostatic hyperplasia.	Compliance with Authority Required procedures - Streamlined Authority Code 15004
Electrolyte replacement, oral	C5889	P5889		For treatment of a patient identifying as Aboriginal or Torres Strait Islander	
	C6786	P6786		Rehydration in intestinal failure	Compliance with Authority Required procedures
Eletriptan	C5141			Migraine attack The condition must have usually failed to respond to analgesics in the past.	
Elotuzumab	C12847			Relapsed and/or refractory multiple myeloma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with lenalidomide and dexamethasone; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an	Compliance with Authority Required procedures

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				absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	
	C12891			Relapsed and/or refractory multiple myeloma Initial treatment The condition must be confirmed by a histological diagnosis; AND The treatment must be in combination with lenalidomide and dexamethasone; AND Patient must have progressive disease after at least one prior therapy; AND Patient must have undergone or be ineligible for a stem cell transplant; AND Patient must not have previously received this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	
Empagliflozin	C4991	P4991		Diabetes mellitus type 2 The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical	Compliance with Authority Required procedures - Streamlined Authority Code 4991

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				records.	
	C5629	P5629		Diabetes mellitus type 2 The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.	Compliance with Authority Required procedures - Streamlined Authority Code 5629
	C7495	P7495		Diabetes mellitus type 2 Continuing treatment	Compliance with Authority Required

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must be in combination with metformin; AND The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.	procedures - Streamlined Authority Code 7495
	C7506	P7506		Diabetes mellitus type 2 The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with a gliptin and an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.	Compliance with Authority Required procedures - Streamlined Authority Code 7506

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C7528	P7528		Diabetes mellitus type 2 Initial treatment The treatment must be in combination with metformin; AND The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a gliptin; OR Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin. The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 7528
	C14471	P14471		Chronic heart failure Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug; AND Patient must have a documented left ventricular ejection fraction (LVEF) of greater than 40%; AND Patient must have documented evidence of structural changes in the heart on echocardiography that would be expected to cause diastolic dysfunction (e.g. left ventricular hypertrophy); AND	Compliance with Authority Required procedures - Streamlined Authority Code 14471

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have documented evidence of at least one of the following: (i) diastolic dysfunction with high filling pressure on echocardiography, stress echocardiography or cardiac catheterisation; (ii) hospitalisation for heart failure in the 12 months prior to initiating treatment with this drug; (iii) requirement for intravenous diuretic therapy in the 12 months prior to initiating treatment with this drug; (iv) elevated N-terminal pro brain natriuretic peptide (NT-proBNP) levels in the absence of another cause; AND Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.	
	C14859	P14859		Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 14859
	C14905	P14905		Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-	Compliance with Authority Required procedures - Streamlined Authority Code 14905

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with a gliptin and an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.	
	C14949	P14949		Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 14949

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.	
	C14974	P14974		Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels	Compliance with Authority Required procedures - Streamlined Authority Code 14974

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.	
	C15047	P15047		Chronic heart failure Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug; AND Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%; AND The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15047
	C15051	P15051		Chronic heart failure The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND	Compliance with Authority Required procedures - Streamlined

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug; AND Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%; AND The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.	Authority Code 15051
Empagliflozin with linagliptin	C7524	P7524		Diabetes mellitus type 2 Initial treatment The treatment must be in combination with metformin; AND Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a dipeptidyl peptidase 4 inhibitor (gliptin) or a sodium-glucose co-transporter 2 (SGLT2) inhibitor; OR Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin. The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 7524

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.	
	C7556	P7556		Diabetes mellitus type 2 Continuing treatment The treatment must be in combination with metformin; AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 7556
	C14885	P14885		Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 14885
Empagliflozin with metformin	C5657	P5657		Diabetes mellitus type 2 The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR	Compliance with Authority Required procedures - Streamlined Authority Code 5657

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.	
	C5798	P5798		Diabetes mellitus type 2 The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 5798

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.	
	C5953	P5953		Diabetes mellitus type 2 Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months	Compliance with Authority Required procedures - Streamlined Authority Code 5953

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.	
	C5966	P5966		Diabetes mellitus type 2 Continuing treatment Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and empagliflozin.	Compliance with Authority Required procedures - Streamlined Authority Code 5966
	C7492	P7492		Diabetes mellitus type 2 Continuing treatment The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 7492
	C7498	P7498		Diabetes mellitus type 2 Initial treatment The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and a gliptin for this condition; OR Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin. The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels	Compliance with Authority Required procedures - Streamlined Authority Code 7498

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.	
	C14878	P14878		Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical	Compliance with Authority Required procedures - Streamlined Authority Code 14878

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.	
	C14881	P14881		Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 14881

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C14924	P14924		Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 14924
	C14925	P14925		Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and empagliflozin.	Compliance with Authority Required procedures - Streamlined Authority Code 14925
Emtricitabine with rilpivirine with tenofovir alafenamide	C4470			HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection.	Compliance with Authority Required procedures - Streamlined Authority Code 4470
	C4522			HIV infection Initial Patient must be antiretroviral treatment naive.	Compliance with Authority Required procedures - Streamlined Authority Code 4522
Emtricitabine with tenofovir alafenamide	C4454			HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512			HIV infection Initial	Compliance with Authority Required

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				Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents.	procedures - Streamlined Authority Code 4512
Enalapril		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Enalapril with hydrochlorothiazide	C4389	P4389		Hypertension The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an ACE inhibitor; OR The condition must be inadequately controlled with a thiazide diuretic.	
	C14280	P14280		Hypertension The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an ACE inhibitor; OR The condition must be inadequately controlled with a thiazide diuretic.	
Encorafenib	C6013	P6013		Unresectable Stage III or Stage IV malignant melanoma Continuing treatment Patient must have previously been issued with an authority prescription for this drug; AND Patient must have stable or responding disease.	Compliance with Authority Required procedures - Streamlined Authority Code 6013
	C10271	P10271		Unresectable Stage III or Stage IV malignant melanoma Initial treatment The condition must be positive for a BRAF V600 mutation; AND The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; OR Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal; AND Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage	Compliance with Authority Required procedures - Streamlined Authority Code 10271

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				IIIB, IIIC or IIID melanoma; AND Patient must have a WHO performance status of 2 or less.	
	C12484	P12484		Metastatic colorectal cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with cetuximab; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 12484
	C12487	P12487		Metastatic colorectal cancer Initial treatment Patient must have BRAF V600 variant positive metastatic colorectal cancer; AND The treatment must be in combination with cetuximab; AND Patient must not have received prior treatment with cetuximab for this condition; OR Patient must not have developed disease progression while receiving cetuximab for this condition; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND The condition must have failed to respond to at least one other line of systemic therapy; AND Patient must have a WHO performance status of 2 or less.	Compliance with Authority Required procedures - Streamlined Authority Code 12487
Enfortumab vedotin	C14416			Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer The condition must have progressed on/following both: (i) platinum-based chemotherapy, (ii) programmed cell death 1/ligand 1 (PD-1/PD-L1) inhibitor therapy; OR The condition must have progressed on/following platinum-based chemotherapy, whilst PD-1/PD-L1 inhibitor therapy resulted in an intolerance that required treatment cessation; AND Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this	Compliance with Authority Required procedures - Streamlined Authority Code 14416

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				PBS indication. Patient must be undergoing treatment with this drug for the first time; OR Patient must be undergoing continuing treatment with this drug, with each of the following being true: (i) all other PBS eligibility criteria in this restriction are met, (ii) disease progression is absent.	
Enoxaparin		P4910		Haemodialysis	
Entacapone	C5133			Parkinson disease The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination; AND Patient must be experiencing fluctuations in motor function due to end-of-dose effect.	
Entecavir	C4993			Chronic hepatitis B infection Patient must not have cirrhosis; AND Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection; AND Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.	Compliance with Authority Required procedures - Streamlined Authority Code 4993
	C5036			Chronic hepatitis B infection Patient must have cirrhosis; AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 5036
	C5037			Chronic hepatitis B infection Patient must have cirrhosis; AND	Compliance with Authority Required

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have failed lamivudine; AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	procedures - Streamlined Authority Code 5037
	C5044			Chronic hepatitis B infection Patient must not have cirrhosis; AND Patient must have failed lamivudine; AND Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.	Compliance with Authority Required procedures - Streamlined Authority Code 5044
Entrectinib	C13184			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND Patient must have a WHO performance status of 2 or less; AND Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; OR Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal; AND Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.	Compliance with Authority Required procedures

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				Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be documented in the patient's medical records: (a) evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.	
	C13276			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures
Enzalutamide	C12895	P12895		Castration resistant non-metastatic carcinoma of the prostate The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition; AND The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation; AND Patient must not receive PBS-subsidised treatment with this drug if progressive	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				disease develops while on this drug; AND Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation. Patient must be undergoing concurrent treatment with androgen deprivation therapy. Prescribing instructions: Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application. The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.	
	C12937	P12937		Castration resistant metastatic carcinoma of the prostate The treatment must not be used in combination with chemotherapy; AND Patient must have a WHO performance status of 2 or less; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.	Compliance with Authority Required procedures
	C14034	P14034		Metastatic castration sensitive carcinoma of the prostate The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy; AND Patient must only receive subsidy for one novel hormonal drug per lifetime for	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug. Patient must be undergoing concurrent androgen deprivation therapy.	
Eplerenone	C4937	P4937		Heart failure with a left ventricular ejection fraction of 40% or less The condition must occur within 3 to 14 days following an acute myocardial infarction; AND The treatment must be commenced within 14 days of an acute myocardial infarction. The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated	Compliance with Authority Required procedures - Streamlined Authority Code 4937
	C14266	P14266		Heart failure with a left ventricular ejection fraction of 40% or less The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must occur within 3 to 14 days following an acute myocardial infarction; AND The treatment must be commenced within 14 days of an acute myocardial infarction. The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated	Compliance with Authority Required procedures - Streamlined Authority Code 14266
Epoetin alfa	C6294			Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6294
	C9688			Anaemia associated with intrinsic renal disease Patient must require transfusion; AND	Compliance with Authority Required

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				Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	procedures - Streamlined Authority Code 9688
Epoetin beta	C6294			Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6294
	C9688			Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9688
Epoetin lambda	C6294			Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6294
	C9688			Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9688
Eprosartan		P6328	CN6328	Drug interactions expected to occur with all of the base-priced drugs	Compliance with Authority Required procedures
		P6329	CN6329	Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance	Compliance with Authority Required procedures
		P6332	CN6332	Drug interactions occurring with all of the base-priced drugs	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
		P6351	CN6351	Adverse effects occurring with all of the base-priced drugs	Compliance with Authority Required procedures
		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
		P14841	CN14841	Drug interactions expected to occur with all of the base-priced drugs The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	Compliance with Authority Required procedures
		P14969	CN14969	Adverse effects occurring with all of the base-priced drugs The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	Compliance with Authority Required procedures
		P14970	CN14970	Drug interactions occurring with all of the base-priced drugs The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	Compliance with Authority Required procedures
		P15009	CN15009	Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	Compliance with Authority Required procedures
Eprosartan with hydrochlorothiazide	C4374			Hypertension The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an angiotensin II antagonist; OR The condition must be inadequately controlled with a thiazide diuretic.	
Eptinezumab	C12029	P12029		Chronic migraine Continuing treatment Must be treated by a specialist neurologist or in consultation with a specialist neurologist; AND Patient must not be undergoing concurrent treatment with the following PBS benefits:	Compliance with Authority Required procedures - Streamlined Authority Code 12029

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				(i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of migraine days per month; AND Patient must continue to be appropriately managed for medication overuse headache. Patient must have the number of migraine days per month documented in their medical records.	
	C14189	P14189		Chronic migraine Initial treatment Must be treated by a neurologist; AND Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication. Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition; AND Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition; AND Patient must be appropriately managed by their practitioner for medication overuse headache, prior to initiation of treatment with this drug. Patient must be at least 18 years of age. Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate. Patient must have the number of migraine days per month documented in their medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 14189
Eribulin	C4649			Locally advanced or metastatic breast cancer Patient must have progressive disease; AND	Compliance with Authority Required

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have failed at least two prior chemotherapeutic regimens for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition.	procedures - Streamlined Authority Code 4649
	C7258			Advanced (unresectable and/or metastatic) liposarcoma Initial treatment Patient must have an ECOG performance status of 2 or less; AND The condition must be dedifferentiated, myxoid, round-cell or pleomorphic subtype; AND Patient must have received prior chemotherapy treatment including an anthracycline and ifosfamide (unless contraindicated) for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be aged 18 years or older.	Compliance with Authority Required procedures - Streamlined Authority Code 7258
	C7280			Advanced (unresectable and/or metastatic) liposarcoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop progressive disease while being treated with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be aged 18 years or older.	Compliance with Authority Required procedures - Streamlined Authority Code 7280
Erlotinib	C4473			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment The treatment must be as monotherapy; AND The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal; AND	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have a WHO performance status of 2 or less. Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.	
	C4600			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be as monotherapy; AND Patient must have previously been issued with an authority prescription for this drug prior to 1 August 2014; AND Patient must not have progressive disease. Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type.	Compliance with Authority Required procedures - Streamlined Authority Code 4600
	C7446			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be as monotherapy; AND Patient must have received an initial authority prescription for this drug for this condition; AND Patient must not have progressive disease. Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.	Compliance with Authority Required procedures - Streamlined Authority Code 7446
Erythromycin		P6160	CN6160	Severe acne The condition must be one in which tetracycline therapy is inappropriate.	Compliance with Authority Required procedures - Streamlined Authority Code 6160
Escitalopram	C4680			Major depressive disorders	

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	C4681			Moderate to severe social anxiety disorder (social phobia, SAD) The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must have been assessed by a psychiatrist.	
	C4690			Moderate to severe social anxiety disorder (social phobia, SAD) The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must have been assessed by a psychiatrist.	
	C4703			Moderate to severe generalised anxiety disorder (GAD) The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.	
	C4707			Moderate to severe generalised anxiety disorder (GAD) The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must have been assessed by a psychiatrist.	
	C4721			Moderate to severe social anxiety disorder (social phobia, SAD) The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.	
	C4747			Moderate to severe generalised anxiety disorder (GAD) The condition must be defined by Diagnostic and Statistical Manual of Mental	

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				Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.	
	C4755			Major depressive disorders	
	C4756			Moderate to severe generalised anxiety disorder (GAD) The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must have been assessed by a psychiatrist.	
	C4757			Moderate to severe social anxiety disorder (social phobia, SAD) The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.	
Esomeprazole	C8774	P8774		Gastro-oesophageal reflux disease The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.	Compliance with Authority Required procedures - Streamlined Authority Code 8774
	C8775	P8775		Peptic ulcer Initial treatment Patient must have tested negative for helicobacter pylori infection; OR Patient must have failed treatment with helicobacter pylori eradication therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 8775
	C8776	P8776		Gastro-oesophageal reflux disease The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton	Compliance with Authority Required procedures - Streamlined

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				pump inhibitor.	Authority Code 8776
	C8777	P8777		Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.	Compliance with Authority Required procedures
	C8778	P8778		Scleroderma oesophagus Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.	Compliance with Authority Required procedures
	C8780	P8780		Scleroderma oesophagus	Compliance with Authority Required procedures - Streamlined Authority Code 8780
	C8827	P8827		Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion	Compliance with Authority Required procedures - Streamlined Authority Code 8827
	C8902	P8902		Gastro-oesophageal reflux disease Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.	Compliance with Authority Required procedures
	C11310	P11310		Complex gastro-oesophageal reflux disease (GORD) One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control Must be treated by a gastroenterologist; OR Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; OR	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes. The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI; AND Patient must must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing. Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.	
	C11370	P11370		Complex gastro-oesophageal reflux disease (GORD) One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control Must be treated by a gastroenterologist; OR Must be treated by a surgeon with expertise in the upper gastrointestinal tract. The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI; AND Patient must have symptoms inadequately controlled with each of: (i) a high dose proton pump inhibitor (PPI) administered once daily, (ii) a standard dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR	Compliance with Authority Required procedures

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				Patient must be assessed for the risks/benefits of a step-down in dosing from a high dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing. Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.	
Esomeprazole and clarithromycin and amoxicillin	C6118			Eradication of Helicobacter pylori The condition must be associated with peptic ulcer disease.	
Essential amino acids formula	C4925			Gyrate atrophy of the choroid and retina	
	C4958			Urea cycle disorders	
Essential amino acids formula with minerals and vitamin c	C4925			Gyrate atrophy of the choroid and retina	
	C4958			Urea cycle disorders	
Essential amino acids formula with vitamins and minerals	C4925			Gyrate atrophy of the choroid and retina	
	C4958			Urea cycle disorders	
Estradiol		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Estradiol and estradiol with		P14238		The condition must be stable for the prescriber to consider the listed maximum	

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dydrogesterone				quantity of this medicine suitable for this patient.	
Estradiol and estradiol with norethisterone		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Estradiol with norethisterone		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Estriol		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Etanercept	C7289	P7289		Severe chronic plaque psoriasis Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND The treatment must be as systemic monotherapy (other than methotrexate). Patient must be aged 18 years or older. Must be treated by a dermatologist.	Compliance with Authority Required procedures
	C8839	P8839		Severe chronic plaque psoriasis Subsequent continuing treatment, whole body	Compliance with Written Authority Required

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				Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	procedures

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				A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C8842	P8842		Severe chronic plaque psoriasis First continuing treatment, Face, hand, foot Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for first continuing or subsequent continuing treatment must be	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				performed on the same affected area assessed at baseline. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C8873	P8873		Severe chronic plaque psoriasis Subsequent continuing treatment, Face, hand, foot Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. The most recent PASI assessment must be no more than 1 month old at the time of application. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C8879	P8879		Severe chronic plaque psoriasis	Compliance with

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				Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND The treatment must be as systemic monotherapy (other than methotrexate). Must be treated by a dermatologist.	Authority Required procedures
	C8887	P8887		Severe chronic plaque psoriasis Subsequent continuing treatment, whole body Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with	Compliance with Authority Required procedures - Streamlined Authority Code 8887

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				this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C8955	P8955		Severe chronic plaque psoriasis Subsequent continuing treatment, face, hand, foot Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to their most recent course of treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	Compliance with Authority Required procedures - Streamlined Authority Code 8955

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				A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9064	P9064		Severe psoriatic arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.	Compliance with Authority Required procedures
	C9081	P9081		Severe psoriatic arthritis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.	Compliance with Authority Required procedures

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				Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.	
	C9123	P9123		Severe psoriatic arthritis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and	Compliance with Written Authority Required procedures

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				(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9140	P9140		Severe psoriatic arthritis Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing treatment restriction, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient	

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				will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9156	P9156		Severe psoriatic arthritis Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of	Compliance with Authority Required procedures - Streamlined Authority Code 9156

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				passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9162	P9162		Severe chronic plaque psoriasis First continuing treatment, Whole body Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and	Compliance with Written Authority Required procedures

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				(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9377	P9377		Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug;	Compliance with Written Authority Required procedures

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				AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.	

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				An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C9380	P9380		Severe active juvenile idiopathic arthritis Continuing Treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.	Compliance with Authority Required procedures
	C9386	P9386		Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	
	C9388	P9388		Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C9473	P9473		Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older.	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Active joints are defined as: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count must be no more than 4 weeks old at the time of this application. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C11107	P11107		Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face,	Compliance with Authority Required procedures

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				hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must be as systemic monotherapy (other than methotrexate); AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a dermatologist.	
	C12164	P12164		Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have a documented history of severe active juvenile idiopathic arthritis	Compliance with Written Authority Required procedures

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				with onset prior to the age of 18 years; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. If methotrexate is contraindicated according to the TGA-approved Product	

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				Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.	

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				An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C12261	P12261		Severe chronic plaque psoriasis Balance of supply - Initial 1, 2, 3 or 4 treatment (Whole body, or, face/hand/foot) Must be treated by a dermatologist; AND Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 16 weeks treatment available under any of the initial treatment phases (regardless of the affected body area): (i) Initial 1, (ii) Initial 2, (iii) Initial 3, (iv) Initial 4. The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate; AND The treatment must provide no more than the balance of up to 16 weeks treatment.	Compliance with Authority Required procedures
	C13532	P13532		Severe psoriatic arthritis Initial treatment - Initial 1 (new patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of	Compliance with Written Authority Required procedures

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				up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and	

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				submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C13533	P13533		Severe psoriatic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at	Compliance with Written Authority Required procedures

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				least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in	

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				this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C13538	P13538		Severe chronic plaque psoriasis Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 1 month old at the time of application. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the	Compliance with Written Authority Required procedures

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				continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C13593	P13593		Severe psoriatic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).	Compliance with Written Authority Required procedures

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				All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	

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				Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C13598	P13598		Severe chronic plaque psoriasis Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.	Compliance with Written Authority Required procedures

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				To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C13646	P13646		Severe chronic plaque psoriasis Initial treatment - Initial 2, Whole body (change or recommencement of treatment	Compliance with Written Authority Required

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				after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.	procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C13647	P13647		Severe chronic plaque psoriasis Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND The treatment must be as systemic monotherapy (other than methotrexate); AND	Compliance with Written Authority Required procedures

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				Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 1 month old at the time of application. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C14154			Severe active juvenile idiopathic arthritis	Compliance with

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				Continuing treatment Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application. At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.	Authority Required procedures - Streamlined Authority Code 14154

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				If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C14155			Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony	Compliance with Authority Required procedures - Streamlined Authority Code 14155

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				overgrowth). The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application. At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C14382	P14382		Severe chronic plaque psoriasis Initial treatment - Initial 1, Face, hand, foot (new patient) Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine	Compliance with Written Authority Required procedures

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				for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or	

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				(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 1 month old at the time of application. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the	

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				necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C14427	P14427		Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the	Compliance with Written Authority Required procedures

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				patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 1 month old at the time of application. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless	

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				the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C14483	P14483		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and	

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				(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	
	C14486	P14486		Severe active rheumatoid arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age.	Compliance with Written Authority Required procedures

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				Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the	

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				necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14488	P14488		Severe active rheumatoid arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	Compliance with Authority Required procedures
	C14493	P14493		Severe active rheumatoid arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14498	P14498		Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii)	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of	

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14499	P14499		Severe active rheumatoid arthritis	Compliance with

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be	Authority Required procedures - Streamlined Authority Code 14499

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				used to determine response. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14507	P14507		Severe active rheumatoid arthritis First continuing treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment.	Compliance with Authority Required procedures
	C14508	P14508		Severe chronic plaque psoriasis Completion of course - treatment covering weeks 16 to 24 (Face, hand, foot) Must be treated by a dermatologist; AND Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine. The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate; AND Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose; AND Patient must have demonstrated an adequate response to treatment; AND Patient must not receive more than 8 weeks of treatment with etanercept under this restriction. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:	Compliance with Authority Required procedures - Streamlined Authority Code 14508

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The assessment of response to treatment must be documented in the patient's medical records. The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.	
	C14509	P14509		Severe chronic plaque psoriasis Completion of course - treatment covering weeks 16 to 24 (Whole body) Must be treated by a dermatologist; AND Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine. The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate; AND Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose; AND Patient must have demonstrated an adequate response to treatment; AND Patient must not receive more than 8 weeks of treatment with etanercept under this restriction. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The assessment of response to treatment must be documented in the patient's medical records. The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for	Compliance with Authority Required procedures - Streamlined Authority Code 14509

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				the remainder of 24 weeks treatment.	
	C14513	P14513		Severe chronic plaque psoriasis Initial 1 treatment (Whole body) - biological medicine-naive patient Must be treated by a dermatologist. Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; AND The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate; AND Patient must have lesions present for at least 6 months from the time of initial diagnosis; AND Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction. Patient must be under 18 years of age. Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be documented in the patient's medical records. Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be documented in the patient's medical records. Details of the accepted toxicities including severity can be found on the Services Australia website. The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy: (a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.	Compliance with Authority Required procedures

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				A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of: (i) the name of each prior therapy trialled that meets the above requirements - state at least 2; (ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies); (iii) the PASI score that followed each prior therapy trialled; (iv) the date the PASI scores were determined. Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.	
	C14552	P14552		Severe chronic plaque psoriasis Initial 2 treatment (Face, hand, foot) - Change of treatment Must be treated by a dermatologist. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate; AND Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction. Patient must be under 18 years of age. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value. In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because: (i) there is an absence of an adequate response to that treatment; or (ii) there was an intolerance to that treatment; or (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above. The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.	
	C14553	P14553		Severe chronic plaque psoriasis Initial 4 - Re-treatment (Whole body) Must be treated by a dermatologist. The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate; AND Patient must have a documented history of severe chronic plaque psoriasis of the whole body. Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) a disease flare where the PASI score has worsened (increased) by at least 50%, (ii) the current PASI score has returned above 15. Patient must not have failed more than once to achieve an adequate response with etanercept; AND Patient must not receive more than 16 weeks of treatment with etanercept under this restriction. Patient must be under 18 years of age. Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.	Compliance with Authority Required procedures
	C14554	P14554		Severe chronic plaque psoriasis	Compliance with

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				Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient Must be treated by a dermatologist. Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; AND The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate; AND Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis; AND Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND Patient must not receive more than 16 weeks of treatment with etanercept under this restriction. Patient must be under 18 years of age. Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be documented in the patient's medical records. Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be documented in the patient's medical records. Details of the accepted toxicities including severity can be found on the Services Australia website. The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy: (a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or (b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following	Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				cessation of the last pre-requisite therapy Provide in this authority application, and document in the patient's medical records, each of: (i) the name of each prior therapy trialled that meets the above requirements - state at least 2; (ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies); (iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled; (iv) the dates that response assessments were determined. Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment: (v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe); (vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine. Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.	
	C14576	P14576		Severe chronic plaque psoriasis Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years Must be treated by a dermatologist. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle; AND The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; OR The condition must be limited to the face/hand/foot - all subsequent authority	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				applications to this application will be made under treatment phases that feature the words 'face, hand, foot'; AND Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; OR The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate; AND Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction. Patient must be under 18 years of age. The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.	
	C14577	P14577		Severe chronic plaque psoriasis Initial 4 - Re-treatment (face, hand, foot) Must be treated by a dermatologist. The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate; AND Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot. Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) all PASI sub-measures (redness, thickness, scaling) are rated as 'moderate' to 'severe', (ii) at least 2 of the 3 PASI sub-measures are rated as 'severe' to 'very severe', (iii) the skin area affected has increased by at least 50% since the last administered dose, (iv) the skin area affected is at least 30% of the total skin area of the face/hand/foot. Patient must not have failed more than once to achieve an adequate response with etanercept; AND	Compliance with Authority Required procedures

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				Patient must not receive more than 16 weeks of treatment with etanercept under this restriction. Patient must be under 18 years of age. Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.	
	C14581	P14581		Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records. The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or	

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				(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to prior treatment must be documented in the patient's medical records. The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records: (a) the active joint count, ESR and/or CRP result and date of results; (b) details of prior treatment, including dose and date/duration of treatment. (c) If applicable, details of any contraindications/intolerances. (d) If applicable, the maximum tolerated dose of methotrexate. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this	

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				restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14582	P14582		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or	Compliance with Authority Required procedures

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				(b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	

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				A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	
	C14600	P14600		Severe chronic plaque psoriasis Initial 2 treatment (Whole body) - Change of treatment Must be treated by a dermatologist. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate; AND Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction. Patient must be under 18 years of age. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because: (i) there is an absence of an adequate response to that treatment; or (ii) there was an intolerance to that treatment; or (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above. The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.	Compliance with Authority Required procedures
	C14603	P14603		Severe active rheumatoid arthritis	Compliance with

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				Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.	Authority Required procedures

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				Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records: (a) the active joint count, ESR and/or CRP result and date of result; (b) the most recent biological agent and the date of the last continuing prescription. (c) If applicable, the new baseline scores. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14629	P14629		Severe active rheumatoid arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority Code 14629

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				Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14655	P14655		Ankylosing spondylitis	Compliance with Written

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				Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units	Authority Required procedures

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				(on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14656	P14656		Ankylosing spondylitis Subsequent continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3	

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				treatment restriction.	
	C14662	P14662		Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and	Compliance with Written Authority Required procedures

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				(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14670	P14670		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or	Compliance with Written Authority Required procedures

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				more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.	

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				If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14671	P14671		Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND	Compliance with Authority Required procedures

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				Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with	

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				the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14673	P14673		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy	Compliance with Authority Required procedures

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				and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14683	P14683		Ankylosing spondylitis First continuing treatment	Compliance with Authority Required

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				Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	procedures - Streamlined Authority Code 14683
	C14701	P14701		Ankylosing spondylitis Subsequent continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised	Compliance with Authority Required procedures - Streamlined

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				biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	Authority Code 14701
	C14703	P14703		Ankylosing spondylitis	Compliance with

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				Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	Authority Required procedures
	C14713	P14713		Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Written Authority Required procedures

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				An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14715	P14715		Ankylosing spondylitis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to	Compliance with Authority Required procedures

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				complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	
Ethosuximide		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
Etravirine	C5014			HIV infection The treatment must be in addition to optimised background therapy; AND The treatment must be in combination with other antiretroviral agents; AND Patient must be antiretroviral experienced; AND Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.	Compliance with Authority Required procedures - Streamlined Authority Code 5014
Everolimus	C4351	P4351		Tuberous sclerosis complex (TSC) Initial treatment The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR The condition must be visceral tumours associated with TSC; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not be a candidate for curative surgical resection.	Compliance with Authority Required procedures
	C4812	P4812		Metastatic (Stage IV) breast cancer The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must have acquired endocrine resistance as demonstrated by initial response and then recurrence or progression of disease after treatment with letrozole	Compliance with Authority Required procedures

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				or anastrozole; AND The treatment must be in combination with exemestane. Patient must not be pre-menopausal.	
	C4837	P4837		Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET) Continuing treatment Patient must have previously been issued with an authority prescription for this drug; AND Patient must not have disease progression; AND The treatment must be as monotherapy. Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.	Compliance with Authority Required procedures
	C4861	P4861		Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET) Initial treatment Patient must be symptomatic (despite somatostatin analogues); OR Patient must have disease progression; AND The treatment must be as monotherapy. Disease progression must be documented in the patient's medical records. Patients who have developed progressive disease on sunitinib are not eligible to receive PBS-subsidised everolimus. Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.	Compliance with Authority Required procedures
		P5554	CN5554	Management of cardiac allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 5554
		P5795	CN5795	Management of renal allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND	Compliance with Authority Required procedures - Streamlined

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				The treatment must be under the supervision and direction of a transplant unit.	Authority Code 5795
	C7431	P7431		Tuberous sclerosis complex (TSC) Continuing treatment The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR The condition must be visceral tumours associated with TSC; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have received an initial authority prescription for this drug for this condition; AND Patient must have demonstrated a response to prior treatment.	Compliance with Authority Required procedures - Streamlined Authority Code 7431
	C7432	P7432		Stage IV clear cell variant renal cell carcinoma (RCC) Continuing treatment beyond 3 months Patient must have received an initial authority prescription for this drug for this condition; AND Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND The treatment must be the sole PBS-subsidised therapy for this condition. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.	Compliance with Authority Required procedures - Streamlined Authority Code 7432
	C8262			Refractory seizures associated with tuberous sclerosis complex Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have maintained a response to the PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with at least one anti-epileptic drug; AND Patient must not be a candidate for curative surgery.	Compliance with Authority Required procedures - Streamlined Authority Code 8262
	C8263			Refractory seizures associated with tuberous sclerosis complex Initial treatment Patient must have a confirmed diagnosis of tuberous sclerosis complex (TSC); AND	Compliance with Authority Required

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				Patient must be experiencing a minimum of two partial-onset seizures per week; AND The condition must have failed to be controlled satisfactorily at stable doses of at least two anti-epileptic drugs; AND The treatment must be in combination with at least one anti-epileptic drug; AND Patient must not be a candidate for curative surgery. Patient must be at least 2 years of age.	procedures
	C8622	P8622		Stage IV clear cell variant renal cell carcinoma (RCC) Initial treatment Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor; AND Patient must have a WHO performance status of 2 or less; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus. Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.	Compliance with Authority Required procedures
		P9691	CN9691	Management of renal allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9691
		P9693	CN9693	Management of cardiac allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9693
		P14238		The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	

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Evolocumab	C10388	P10388		Familial homozygous hypercholesterolaemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in conjunction with dietary therapy and exercise.	Compliance with Authority Required procedures - Streamlined Authority Code 10388
	C12010	P12010		Non-familial hypercholesterolaemia Continuing treatment with this drug or switching treatment from another drug within the same pharmacological class Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR Patient must have received PBS-subsidised treatment with a drug from the same pharmacological class as this drug for this PBS indication; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must not be receiving concomitant PBS-subsidised treatment with another drug that belongs to the same pharmacological class as this drug.	Compliance with Authority Required procedures - Streamlined Authority Code 12010
	C12011	P12011		Familial heterozygous hypercholesterolaemia Continuing treatment with this drug or switching treatment from another drug within the same pharmacological class Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR Patient must have received PBS-subsidised treatment with a drug from the same pharmacological class as this drug for this PBS indication; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must not be receiving concomitant PBS-subsidised treatment with another drug that belongs to the same pharmacological class as this drug, for this PBS indication.	Compliance with Authority Required procedures - Streamlined Authority Code 12011
	C13467	P13467		Non-familial hypercholesterolaemia Grandfather treatment Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2022; AND	Compliance with Authority Required procedures

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				The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have had symptomatic atherosclerotic cardiovascular disease prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories) prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had diabetes mellitus with microalbuminuria prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had diabetes mellitus and be aged 60 years of more prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus that was present prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had a Thrombolysis in Myocardial Infarction (TIMI) Risk Score for Secondary Prevention of 4 or higher prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and	

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				rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition. Must be treated by a specialist physician; OR Must be treated by a physician who has consulted a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or	

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				(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal. In the event of a trial of the alternative statin, the dose of the alternative statin should have been increased not more often than every 4 weeks until the maximum tolerated dose was reached or target LDL-c had been achieved. One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event: (i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or (ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or (iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or	

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				(iv) diabetes mellitus with microalbuminuria; or (v) diabetes mellitus and age 60 years of more; or (vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or (vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.	
	C13469	P13469		Familial homozygous hypercholesterolaemia Initial treatment The treatment must be in conjunction with dietary therapy and exercise; AND The condition must have been confirmed by genetic testing; OR The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7; AND Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information. Must be treated by a specialist physician; OR Must be treated by a physician who has consulted a specialist physician. The qualifying LDL cholesterol level following at least 12 consecutive weeks of treatment with a statin (unless treatment with a statin is contraindicated or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.	Compliance with Authority Required procedures

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				A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. The following must be stated at the time of application and documented in the patient's medical records: (i) the qualifying Dutch Lipid Clinic Network Score; or (ii) the result of genetic testing confirming a diagnosis of familial homozygous hypercholesterolaemia One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the dose, duration of treatment and details of adverse events experienced with the trial of atorvastatin or rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information	
	C13563	P13563		Non-familial hypercholesterolaemia Initial treatment The treatment must be in conjunction with dietary therapy and exercise; AND Patient must not be receiving concomitant PBS-subsidised treatment with another drug that belongs to the same pharmacological class as this drug; AND Patient must have symptomatic atherosclerotic cardiovascular disease; AND Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre; AND Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); OR Patient must have severe multi-vessel coronary heart disease defined as at least	Compliance with Authority Required procedures

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				50% stenosis in at least two large vessels; OR Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise. Must be treated by a specialist physician; OR Must be treated by a physician who has consulted a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic	

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				event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal. In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved. One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or	

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				(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event: (i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or (ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or (iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or (iv) diabetes mellitus with microalbuminuria; or (v) diabetes mellitus and age 60 years of more; or (vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or (vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher	
	C13564	P13564		Familial heterozygous hypercholesterolaemia Initial treatment The treatment must be in conjunction with dietary therapy and exercise; AND The condition must have been confirmed by genetic testing; OR The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6; AND Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; OR Patient must have an LDL cholesterol level in excess of 5 millimoles per litre; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR	Compliance with Authority Required procedures

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				Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; AND Patient must not be receiving concomitant PBS-subsidised treatment with another drug that belongs to the same pharmacological class as this drug, for this PBS indication. Must be treated by a specialist physician; OR Must be treated by a physician who has consulted a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is	

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				proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal. In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved. The following must be stated at the time of application and documented in the patient's medical records: (i) the qualifying Dutch Lipid Clinic Network Score; or (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.	
	C13664	P13664		Familial heterozygous hypercholesterolaemia	Compliance with

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				Grandfather treatment Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2022; AND The treatment must be in conjunction with dietary therapy and exercise; AND The condition must have been confirmed by genetic testing prior to starting non-PBS-subsidised treatment with this drug for this condition; OR The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6 prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease at the time non-PBS-subsidised treatment with this drug for this condition was initiated; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition. Must be treated by a specialist physician; OR Must be treated by a physician who has consulted a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on	Authority Required procedures

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				imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal.	

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				In the event of a trial of the alternative statin, the dose of the alternative statin should have been increased not more often than every 4 weeks until the maximum tolerated dose was reached or target LDL-c had been achieved. The following must be stated at the time of application and documented in the patient's medical records: (i) the qualifying Dutch Lipid Clinic Network Score; or (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.	
Exemestane	C4796	P4796		Metastatic (Stage IV) breast cancer The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND Patient must be receiving PBS-subsidised everolimus concomitantly for this condition. Patient must not be pre-menopausal.	
	C5522	P5522		Breast cancer The condition must be hormone receptor positive.	
	C14992	P14992		Breast cancer The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND	

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				The condition must be hormone receptor positive.	
	C15031	P15031		Metastatic (Stage IV) breast cancer The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND Patient must be receiving PBS-subsidised everolimus concomitantly for this condition. Patient must not be pre-menopausal.	
Ezetimibe	C7966	P7966		Hypercholesterolaemia Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose; OR Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of the statin treatment; OR Patient must be one in whom treatment with an HMG CoA reductase inhibitor (statin) is contraindicated; AND Patient must have coronary heart disease; OR Patient must have cerebrovascular disease; OR Patient must have peripheral vascular disease; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR Patient must have heterozygous familial hypercholesterolaemia; OR Patient must have homozygous familial hypercholesterolaemia; OR	Compliance with Authority Required procedures - Streamlined Authority Code 7966

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				Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females. The type and severity of the adverse event or contraindication must be documented in the patient's medical records.	
	C7990	P7990		Hypercholesterolaemia Patient must have homozygous sitosterolaemia.	Compliance with Authority Required procedures - Streamlined Authority Code 7990
	C7996	P7996		Hypercholesterolaemia The treatment must be in conjunction with dietary therapy and exercise; AND The treatment must be co-administered with an HMG CoA reductase inhibitor (statin); AND Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND Patient must have coronary heart disease; OR Patient must have cerebrovascular disease; OR Patient must have peripheral vascular disease; OR	Compliance with Authority Required procedures - Streamlined Authority Code 7996

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have diabetes mellitus with microalbuminuria; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR Patient must have heterozygous familial hypercholesterolaemia; OR Patient must have homozygous familial hypercholesterolaemia; OR Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin. The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated. Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.	
	C14249	P14249		Hypercholesterolaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in conjunction with dietary therapy and exercise; AND The treatment must be co-administered with an HMG CoA reductase inhibitor (statin); AND Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND	Compliance with Authority Required procedures - Streamlined Authority Code 14249

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have coronary heart disease; OR Patient must have cerebrovascular disease; OR Patient must have peripheral vascular disease; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR Patient must have heterozygous familial hypercholesterolaemia; OR Patient must have homozygous familial hypercholesterolaemia; OR Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin. The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated. Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.	
	C14283	P14283		Hypercholesterolaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a	Compliance with Authority Required procedures - Streamlined Authority Code 14283

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				reduction in the statin dose; OR Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of the statin treatment; OR Patient must be one in whom treatment with an HMG CoA reductase inhibitor (statin) is contraindicated; AND Patient must have coronary heart disease; OR Patient must have cerebrovascular disease; OR Patient must have peripheral vascular disease; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR Patient must have heterozygous familial hypercholesterolaemia; OR Patient must have homozygous familial hypercholesterolaemia; OR Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or	

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				greater than 3.5 for females. The type and severity of the adverse event or contraindication must be documented in the patient's medical records.	
	C14310	P14310		Hypercholesterolaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have homozygous sitosterolaemia.	Compliance with Authority Required procedures - Streamlined Authority Code 14310
Ezetimibe and rosuvastatin	C7957	P7957		Hypercholesterolaemia The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND Patient must have coronary heart disease; OR Patient must have cerebrovascular disease; OR Patient must have peripheral vascular disease; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR Patient must have heterozygous familial hypercholesterolaemia; OR Patient must have homozygous familial hypercholesterolaemia; OR Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin. The dose and duration of statin treatment and the cholesterol concentration which	Compliance with Authority Required procedures - Streamlined Authority Code 7957

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				shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated. Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.	
	C7958	P7958		Hypercholesterolaemia The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose; AND Patient must have coronary heart disease; OR Patient must have cerebrovascular disease; OR Patient must have peripheral vascular disease; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR Patient must have heterozygous familial hypercholesterolaemia; OR Patient must have homozygous familial hypercholesterolaemia; OR Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is	Compliance with Authority Required procedures - Streamlined Authority Code 7958

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				proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females. The type and severity of the adverse event or contraindication must be documented in the patient's medical records.	
	C14284	P14284		Hypercholesterolaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND Patient must have coronary heart disease; OR Patient must have cerebrovascular disease; OR Patient must have peripheral vascular disease; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR Patient must have heterozygous familial hypercholesterolaemia; OR Patient must have homozygous familial hypercholesterolaemia; OR Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease	Compliance with Authority Required procedures - Streamlined Authority Code 14284

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				Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin. The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated. Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.	
	C14350	P14350		Hypercholesterolaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose; AND Patient must have coronary heart disease; OR Patient must have cerebrovascular disease; OR Patient must have peripheral vascular disease; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR	Compliance with Authority Required procedures - Streamlined Authority Code 14350

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have heterozygous familial hypercholesterolaemia; OR Patient must have homozygous familial hypercholesterolaemia; OR Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females. The type and severity of the adverse event or contraindication must be documented in the patient's medical records.	
Ezetimibe with atorvastatin	C7957	P7957		Hypercholesterolaemia The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND Patient must have coronary heart disease; OR Patient must have cerebrovascular disease; OR Patient must have peripheral vascular disease; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR	Compliance with Authority Required procedures - Streamlined Authority Code 7957

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR Patient must have heterozygous familial hypercholesterolaemia; OR Patient must have homozygous familial hypercholesterolaemia; OR Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin. The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated. Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.	
	C7958	P7958		Hypercholesterolaemia The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose; AND Patient must have coronary heart disease; OR Patient must have cerebrovascular disease; OR Patient must have peripheral vascular disease; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have diabetes mellitus and be aged 60 years or more; OR	Compliance with Authority Required procedures - Streamlined Authority Code 7958

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR Patient must have heterozygous familial hypercholesterolaemia; OR Patient must have homozygous familial hypercholesterolaemia; OR Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females. The type and severity of the adverse event or contraindication must be documented in the patient's medical records.	
	C14269	P14269		Hypercholesterolaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a	Compliance with Authority Required procedures - Streamlined Authority Code 14269

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				reduction in the statin dose; AND Patient must have coronary heart disease; OR Patient must have cerebrovascular disease; OR Patient must have peripheral vascular disease; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR Patient must have heterozygous familial hypercholesterolaemia; OR Patient must have homozygous familial hypercholesterolaemia; OR Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females. The type and severity of the adverse event or contraindication must be documented in the patient's medical records.	
	C14284	P14284		Hypercholesterolaemia	Compliance with

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND Patient must have coronary heart disease; OR Patient must have cerebrovascular disease; OR Patient must have peripheral vascular disease; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR Patient must have heterozygous familial hypercholesterolaemia; OR Patient must have homozygous familial hypercholesterolaemia; OR Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin. The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated. Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.	Authority Required procedures - Streamlined Authority Code 14284

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C14348	P14348		Hypercholesterolaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND Patient must have coronary heart disease; OR Patient must have cerebrovascular disease; OR Patient must have peripheral vascular disease; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR Patient must have heterozygous familial hypercholesterolaemia; OR Patient must have homozygous familial hypercholesterolaemia; OR Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin. The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated. Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or	Compliance with Authority Required procedures - Streamlined Authority Code 14348

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				greater than 3.5 for females.	
Ezetimibe with simvastatin	C7957	P7957		Hypercholesterolaemia The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND Patient must have coronary heart disease; OR Patient must have cerebrovascular disease; OR Patient must have peripheral vascular disease; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR Patient must have heterozygous familial hypercholesterolaemia; OR Patient must have homozygous familial hypercholesterolaemia; OR Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin. The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated. Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.	Compliance with Authority Required procedures - Streamlined Authority Code 7957

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
	C7958	P7958		Hypercholesterolaemia The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose; AND Patient must have coronary heart disease; OR Patient must have cerebrovascular disease; OR Patient must have peripheral vascular disease; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR Patient must have heterozygous familial hypercholesterolaemia; OR Patient must have homozygous familial hypercholesterolaemia; OR Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.	Compliance with Authority Required procedures - Streamlined Authority Code 7958

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females. The type and severity of the adverse event or contraindication must be documented in the patient's medical records.	
	C14269	P14269		Hypercholesterolaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose; AND Patient must have coronary heart disease; OR Patient must have cerebrovascular disease; OR Patient must have peripheral vascular disease; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR Patient must have heterozygous familial hypercholesterolaemia; OR Patient must have homozygous familial hypercholesterolaemia; OR Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is	Compliance with Authority Required procedures - Streamlined Authority Code 14269

Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females. The type and severity of the adverse event or contraindication must be documented in the patient's medical records.	
	C14284	P14284		Hypercholesterolaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND Patient must have coronary heart disease; OR Patient must have cerebrovascular disease; OR Patient must have peripheral vascular disease; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR Patient must have heterozygous familial hypercholesterolaemia; OR Patient must have homozygous familial hypercholesterolaemia; OR Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease	Compliance with Authority Required procedures - Streamlined Authority Code 14284

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Listed Drug	Circumstances Code	Purposes Code	Conditions Code	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin. The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated. Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.	