

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

**Volume 5: Schedule 4 (Part 1: A–E)**

Volume 6: Schedule 4 (Part 1: F–R)

Volume 7: Schedule 4 (Part 1: S–Z, Part 3), Schedule 5 and  
 Endnotes

Each volume has its own contents

**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 December 2023 (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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.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

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 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. | Compliance with Authority Required 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 available under the above restrictions. | Compliance with Authority Required procedures |
|  | 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 (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. | Compliance with Written Authority Required procedures |
|  | C14522 | P14522 |  | 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 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. 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 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 this drug for this condition. | Compliance with Written Authority Required procedures |
|  | 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. 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14555 |
|  | 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; 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. 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. | Compliance with Written Authority Required procedures |
|  | 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 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 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 medicine. | Compliance with Written Authority Required procedures |
|  | 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. 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14604 |
| 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 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. | Compliance with Authority Required procedures |
|  | 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 |
| 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 |
| Acalabrutinib | C12495 |  |  | 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 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. | Compliance with Authority Required procedures |
|  | C12500 |  |  | 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 |
|  | C14344 |  |  | 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 with this drug where prior, active 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; OR Patient must be undergoing treatment through this treatment phase listing on a subsequent occasion, with disease progression being absent. | 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 Authority Code 5366 |
| 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 |
| 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 |
| 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 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. | Compliance with Authority Required procedures |
| 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 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. | Compliance with Authority Required procedures |
| 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 11523 |
| 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. 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. | Compliance with Authority Required procedures - Streamlined Authority Code 11524 |
| 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 11579 |
| 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. 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 11604 |
| 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. 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 11606 |
| 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. 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. | Compliance with Authority Required procedures - Streamlined Authority Code 11631 |
| 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 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures |
|  | 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 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 necessity for permanent withdrawal of treatment. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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 (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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 11718 |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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 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. | Compliance with Authority Required procedures |
|  | 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. 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 treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
|  | 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 (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. | Compliance with Written Authority Required procedures |
|  | C11861 | P11861 |  | Severe psoriatic arthritis 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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 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. | Compliance with Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures |
|  | 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: (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. | Compliance with Written Authority Required procedures |
|  | 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 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 this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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 (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. 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. | Compliance with Written Authority Required procedures |
|  | 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 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 |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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 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 Written Authority Required procedures |
|  | 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. 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. | Compliance with Written Authority Required procedures |
|  | 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 Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | C12212 | P12212 |  | 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 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. 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. | Compliance with Written Authority Required procedures |
|  | 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. 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures |
|  | 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: (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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | C12306 | P12306 |  | Moderate to severe hidradenitis suppurativa 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. | Compliance with Written 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. 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. | Compliance with Written Authority Required procedures |
|  | 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 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 adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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. 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. | Compliance with Written Authority Required procedures |
|  | 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 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 (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. 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. | Compliance with Written Authority Required procedures |
|  | 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 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. 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. | Compliance with Written Authority Required procedures |
|  | 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. 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. | Compliance with Written Authority Required procedures |
|  | 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 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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 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 failure. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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. 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14107 |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14136 |
|  | 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. 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]. 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. | Compliance with Written Authority Required procedures |
|  | 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 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 (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. | Compliance with Written Authority Required procedures |
|  | 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. 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 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. | Compliance with Written Authority Required procedures |
|  | 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, 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]. 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. | Compliance with Written Authority Required procedures |
|  | 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; 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 (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. | Compliance with Written Authority Required procedures |
|  | 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. 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. 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. 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. | Compliance with Authority Required procedures |
|  | 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) 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14499 |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14567 |
|  | 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 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. 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. | Compliance with Authority Required procedures |
|  | 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 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 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. | Compliance with Authority Required procedures |
|  | 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 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 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. | Compliance with Written Authority Required procedures |
|  | 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 (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. | Compliance with Written Authority Required procedures |
|  | 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 (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. | Compliance with Written Authority Required procedures |
|  | 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 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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 necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Authority Required procedures |
|  | 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: (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. | Compliance with Authority Required procedures |
|  | 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: (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. | Compliance with Authority Required 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14701 |
|  | 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). 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. | Compliance with Written Authority Required procedures |
|  | C14730 | P14730 |  | 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 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. | Compliance with Authority Required 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 |
| 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) 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. | Compliance with Authority Required 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 |
|  | 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 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 |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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: (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 |
|  | 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 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 13406 |
|  | 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 |
| 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 treatment with this drug for this condition. | Compliance with Authority Required procedures |
| 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 |
|  | 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. 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 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 with colecalciferol | C6306 |  |  | 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 6306 |
| C6307 |  |  | 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 |  |  | 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 |  |  | 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 6319 |
| C6320 |  |  | 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 |  |  | 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 |
| Alirocumab | C12008 |  |  | 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 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 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 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. | Compliance with Authority Required procedures |
| 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 |
| 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 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 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 | Compliance with Authority Required procedures |
| Allopurinol |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
| Alogliptin | C4349 |  |  | 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 |
| Alogliptin with metformin | C4423 |  |  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 4423 |
| C4427 |  |  | 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 |
| 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. |  |
| 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. 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 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 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. 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. 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: (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 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 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, vitamins, minerals and trace elements without phenylalanine | C5970 |  |  | Phenylketonuria |  |
| 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 authority application. | Compliance with Authority Required procedures |
| 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 authority application. | Compliance with Authority Required procedures |
| 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. 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 |  |  | 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. 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 |
| 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 without phenylalanine | C5970 |  |  | Phenylketonuria |  |
| 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 |  |
| 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 |  |
| 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 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. 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 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 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. 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. 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: (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 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 authority application. | Compliance with Authority Required procedures |
| 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 authority application. | Compliance with Authority Required procedures |
| 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. 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 |  |  | 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 medium chain triglycerides | 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. 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 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 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. 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. 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: (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 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. 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 |
| 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 |
| 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. |  |
| 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 Patient must have a condition requiring prolonged oral antibiotic therapy. | Compliance with Authority Required 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 |  |  | Breast cancer 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 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. | 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 |
| 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 |
| 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 |
| 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 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 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 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 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 |
|  | 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 |
|  | 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; 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 6444 |
|  | 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 |  |
| 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 this condition; OR Patient must have previously received PBS-subsidised treatment with modafinil for this condition. | Compliance with Authority Required procedures |
|  | 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 (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. | Compliance with Written Authority Required procedures |
| 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)  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. | Compliance with 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  (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; 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. | Compliance with Written Authority Required procedures |
|  | 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  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  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). | Compliance with Authority Required procedures |
|  | 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  (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 | Compliance with Authority Required procedures |
| 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 |
| 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 10125 |
|  | 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 line of treatment; AND Patient must have stable or responding disease; AND The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10257 |
|  | 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 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 10917 |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined 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 |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 13451 |
| 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 7876 |
| 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 10023 |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined 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  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. | Compliance with Written 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 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. | Compliance with Authority Required procedures |
| 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 Patient must have CD4 cell counts of less than 75 per cubic millimetre. | Compliance with Authority Required procedures - Streamlined 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 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 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 |
| 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 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 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 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 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. | Compliance with Written Authority Required procedures |
|  | 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. 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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 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. | Compliance with Written Authority Required procedures |
|  | 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) 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14499 |
|  | 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 glycopyrronium | 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 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. | Compliance with Authority Required procedures - Streamlined 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 |
|  | 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 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 |  |
| 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 |
|  | 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  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. | Compliance with Authority Required 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 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) 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. | Compliance with Written Authority Required procedures |
|  | 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.  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. | Compliance with Written Authority Required procedures |
|  | 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  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 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 Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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)  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 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. | Compliance with Written Authority Required procedures |
|  | 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.  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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | C14449 | P14449 |  | 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 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. | Compliance with Authority Required 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 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. | Compliance with Written Authority Required procedures |
|  | C14726 | P14726 |  | Severe chronic plaque psoriasis 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. 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. | Compliance with Written Authority Required procedures |
| 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. |  |
| 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. |  |
| 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 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. | Compliance with Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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. 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. | Compliance with Written Authority Required procedures |
| 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 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 |
| 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 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. | Compliance with Authority Required 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 6953 |
| 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 9334 |
| 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 9547 |
| 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 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). | Compliance with Written Authority Required procedures |
|  | 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 (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). | Compliance with Written Authority Required procedures |
|  | 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 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). | Compliance with Written Authority Required procedures |
|  | 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 |
|  | 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 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. | Compliance with Authority Required procedures |
|  | 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 |
|  | 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 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 |
|  | 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 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 10251 |
|  | 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 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. | Compliance with Written Authority Required procedures |
| 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. |  |
| 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 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. | Compliance with 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 mm2hpf; 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 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. | Compliance with 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 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 mm2hpf 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. | Compliance with Authority Required procedures |
| 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 4380 |
| 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 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 12349 |
| 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. 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 10748 |
| 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 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). | Compliance with 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. The treatment must be within a framework of medical, social and psychological treatment. | Compliance with Authority Required 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 |
| 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 |
| 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. |  |
| 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 11880 |
| 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 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. 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 14259 |
|  | 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 hydrochlorothiazide | C4374 | P4374 |  | 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. |  |
| 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 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. | Compliance with Authority Required procedures |
| Captopril | C4996 |  |  | Patients unable to take a solid dose form of an ACE inhibitor. |  |
| 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 Patient must be sensitive to preservatives in multi-dose eye drops. | Compliance with Authority Required 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 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 12694 |
|  | 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 |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 12934 |
|  | 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 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 14363 |
|  | 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 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 14364 |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14389 |
| 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 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 10410 |
|  |  | 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 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 |  |
| 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 13373 |
|  | 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. 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. | Compliance with Authority Required procedures - Streamlined Authority Code 13766 |
| 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 Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. | Compliance with Authority Required procedures |
|  | 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: (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. | Compliance with Written Authority Required procedures |
|  | 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 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 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. | Compliance with Written Authority Required procedures |
|  | 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. 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 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. | Compliance with Written Authority Required procedures |
|  | 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: 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures |
|  | 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 |
|  | 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 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. | Compliance with Authority Required procedures |
|  | C11386 | P11386 |  | Non-radiographic axial spondyloarthritis 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. 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. | Compliance with Written Authority Required procedures |
|  | C12392 | P12392 |  | Non-radiographic axial spondyloarthritis 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 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. | Compliance with Authority Required 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 (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. | 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 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14499 |
|  | 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 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. | Compliance with Authority Required procedures |
|  | 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 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 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. | Compliance with Written Authority Required procedures |
|  | C14591 | P14591 |  | 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 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 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 PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | C14659 | P14659 |  | 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 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 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 failure. | Compliance with Written Authority Required procedures |
|  | 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: (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. | Compliance with Written Authority Required procedures |
|  | 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 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 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 Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
| 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 |
| 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 The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 4912 |
|  | 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 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 12045 |
|  | 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, 13202 or 13203 of the Medicare Benefits Schedule. Patient must not be undergoing simultaneous treatment with this drug through another PBS program listing. | Compliance with Authority Required 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 |
|  | 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 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 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) 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 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. 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). | Compliance with Authority Required procedures |
|  | 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 treatment authority application). | Compliance with Authority Required procedures |
| 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 tolerability. | Compliance with Authority Required procedures - Streamlined Authority Code 10067 |
|  | 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. 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. | Compliance with Authority Required procedures |
| 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 resistant to all other appropriate antimicrobials. | Compliance with Authority Required procedures |
| 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 |  |
| 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. 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 10170 |
|  | 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 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. | Compliance with Authority Required 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. |  |
| 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. 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 |
| 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 9334 |
| 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. Standard management includes physiotherapy and/or oral spasticity agents. | Compliance with Authority Required procedures - Streamlined Authority Code 9547 |
| 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. 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 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 (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 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 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 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. 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. 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 |
| 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 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. | Compliance with Authority Required procedures |
|  | 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) 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. | Compliance with Authority Required procedures |
|  | 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 |
| 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 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. | Compliance with 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 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. | Compliance with Authority Required procedures |
|  | 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 |  |  | 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 records. | Compliance with Authority Required procedures - Streamlined Authority Code 4991 |
| C5629 |  |  | 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 |  |  | 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 |  |  | 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 |
| C7528 |  |  | 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 |
|  | C12477 |  |  | Chronic heart failure Patient must be symptomatic with NYHA classes II, III or IV; 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 12477 |
|  | C13230 |  |  | 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 m2inclusive 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 |
| Dapagliflozin with metformin | C5631 |  |  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 5631 |
| C5657 |  |  | 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 records. | Compliance with Authority Required procedures - Streamlined Authority Code 5657 |
| C5739 |  |  | 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 |  |  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 5798 |
| C7492 |  |  | 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 |  |  | 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 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 7498 |
| 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 (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 |
|  | 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 (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 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. | Compliance with Authority Required procedures |
|  | 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 (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 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. | Compliance with Authority Required procedures |
|  | 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 (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 |
|  | 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 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 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. | Compliance with Authority Required procedures |
|  | 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. 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. | Compliance with Written Authority Required procedures |
|  | 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 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). | Compliance with Written Authority Required procedures |
| 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; 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. | 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 |
| 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 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 6377 |
| 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 |
| 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; (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. | Compliance with Written Authority Required procedures |
|  | 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 |
|  | 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 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 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. | Compliance with Authority Required procedures |
|  | 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% 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 12530 |
|  | 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 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% 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. | Compliance with Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures |
| 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 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. | Compliance with 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 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. | Compliance with Authority Required procedures |
| 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 |
| 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 |
| 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 Patient must be one in whom desferrioxamine therapy has proven ineffective. | Compliance with Authority Required procedures - Streamlined 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 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. | Compliance with Authority Required 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 Authority Code 9696 |
| Desmopressin | C5226 |  |  | 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 |  |  | 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 |
| 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 |
| 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 treatment or further intensification of systemic treatment is not clinically indicated. | Compliance with Authority Required procedures |
|  | 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. 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 |
|  | 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) 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
| 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 Patient must be under 18 years of age. | Compliance with Authority Required 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 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. | Compliance with Authority Required 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 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. | Compliance with 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 Patient must have previously received PBS-subsidised therapy for HIV infection. | Compliance with Authority Required procedures - Streamlined 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 13938 |
|  | 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; (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. | Compliance with Authority Required procedures |
|  | 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. 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 5634 |
| 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: (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 5740 |
|  | 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; 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 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. |  |
| 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 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 |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 7645 |
| 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 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. | Compliance with Authority Required procedures |
|  | 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 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 | Compliance with Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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; 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 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. | Compliance with Written Authority Required procedures |
| 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 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. | Compliance with Authority Required procedures - Streamlined 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 |  |  | 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 |
| Dutasteride with tamsulosin | C6189 |  |  | 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 |
| Efavirenz | 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 |
| 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 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 |
|  | 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 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 |
| Empagliflozin | C4991 |  |  | 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 records. | Compliance with Authority Required procedures - Streamlined Authority Code 4991 |
| C5629 |  |  | 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 |  |  | 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 |  |  | 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 |
| C7528 |  |  | 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 |
| C12477 |  |  | Chronic heart failure Patient must be symptomatic with NYHA classes II, III or IV; 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 12477 |
|  | C14471 |  |  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14471 |
| Empagliflozin with linagliptin | C7524 |  |  | 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. 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 7524 |
| C7556 |  |  | 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 |
| Empagliflozin with metformin | C5657 |  |  | 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 records. | Compliance with Authority Required procedures - Streamlined Authority Code 5657 |
| C5798 |  |  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 5798 |
| C5953 |  |  | 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 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 5953 |
| C5966 |  |  | 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 |  |  | 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 |  |  | 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 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 7498 |
| 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 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 |
| 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 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 10271 |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14416 |
| 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 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. | Compliance with Authority Required 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. 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. | Compliance with Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures |
|  | 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 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 |
| 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 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 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 |
|  | P6351 | CN6351 | Adverse effects occurring with all of the base-priced drugs | 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: (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. | Compliance with Authority Required procedures - Streamlined Authority Code 12029 |
|  | 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 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. | Compliance with Authority Required 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 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. | Compliance with Authority Required procedures |
| 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 |
| Ertugliflozin | C7495 |  |  | 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 |  |  | 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 |
|  | C7528 |  |  | 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 |
| Ertugliflozin with sitagliptin | C7524 |  |  | 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.  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 7524 |
|  | C7556 |  |  | 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 |
| 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 |  |
| 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 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 pump inhibitor. | Compliance with Authority Required procedures - Streamlined 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 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. | Compliance with Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures |
| 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 |  |
| 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 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. 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 Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | C8879 | P8879 |  | 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; 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 |
|  | 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 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 8887 |
|  | 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. 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 8955 |
|  | 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. 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 |
|  | 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 (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. | Compliance with Written Authority Required procedures |
|  | 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 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 9156 |
|  | 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 (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. | Compliance with Written Authority Required procedures |
|  | 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; 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. 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. | Compliance with Written Authority Required procedures |
|  | 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 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 |
|  | 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: (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. 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. | Compliance with Written Authority Required procedures |
|  | 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. 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures |
|  | 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 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 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. 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. | Compliance with Written Authority Required procedures |
|  | 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 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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 this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | 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). 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. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | 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. 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. | Compliance with Written Authority Required procedures |
|  | C13646 | P13646 |  | 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 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. 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Written Authority Required procedures |
|  | C14154 |  |  | 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. 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14154 |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14155 |
|  | 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 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 (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 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. | Compliance with Written Authority Required procedures |
|  | 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 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 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. | Compliance with Written Authority Required procedures |
|  | 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; 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 (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. | Compliance with Written Authority Required procedures |
|  | 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. 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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 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. | Compliance with Written Authority Required procedures |
|  | 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) 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14499 |
|  | 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: (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. | Compliance with Authority Required procedures - Streamlined Authority Code 14508 |
|  | 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 the remainder of 24 weeks treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 14509 |
|  | 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. 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. | Compliance with Authority Required procedures |
|  | 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 (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. | Compliance with Authority Required procedures |
|  | 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 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 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. | Compliance with Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures |
|  | 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 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 |
|  | 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-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 (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 restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
|  | 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 (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. 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. | Compliance with Authority Required procedures |
|  | 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 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. 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. | Compliance with Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14629 |
|  | 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 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 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. | Compliance with Written Authority Required procedures |
|  | 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 (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. | Compliance with Written Authority Required procedures |
|  | 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 (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. | Compliance with Written Authority Required procedures |
|  | 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 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 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. | Compliance with Written Authority Required procedures |
|  | 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 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 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. | Compliance with Authority Required procedures |
|  | 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: (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. | Compliance with Authority Required procedures |
|  | 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: (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. | Compliance with Authority Required 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14701 |
|  | C14703 | P14703 |  | 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. 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 |
|  | 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). 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. | Compliance with Written Authority Required procedures |
|  | 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 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. | Compliance with Authority Required procedures |
| 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 or anastrozole; AND The treatment must be in combination with exemestane. Patient must not be pre-menopausal. | Compliance with Authority Required procedures |
| 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 The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined 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 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. | Compliance with Authority Required 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 |
| 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 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 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 (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 (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. | Compliance with Authority Required procedures |
|  | 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. 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 | Compliance with Authority Required procedures |
|  | 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 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 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 (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 | Compliance with Authority Required procedures |
|  | 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 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 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. | Compliance with Authority Required procedures |
|  | C13664 | P13664 |  | Familial heterozygous hypercholesterolaemia 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 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. 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. | Compliance with Authority Required procedures |
| Exemestane | C4796 |  |  | 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 |  |  | Breast cancer The condition must be hormone receptor positive. |  |
| 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 7966 |
|  | 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 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 7996 |
|  | 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 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 14249 |
|  | 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 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14283 |
|  | 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 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 |
|  | 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. 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. | Compliance with Authority Required procedures - Streamlined Authority Code 7958 |
|  | 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 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 14284 |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14350 |
| 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 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 |
|  | 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. 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. | Compliance with Authority Required procedures - Streamlined Authority Code 7958 |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14269 |
|  | 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 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 14284 |
|  | 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 greater than 3.5 for females. | Compliance with Authority Required procedures - Streamlined Authority Code 14348 |
| 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 |
|  | 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. 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. | Compliance with Authority Required procedures - Streamlined Authority Code 7958 |
|  | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14269 |
|  | 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 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 14284 |