National Health (Listing of Pharmaceutical Benefits) Instrument 2024

PB 26 of 2024

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

National Health Act 1953

Compilation No. 8

Compilation date: 1 December 2024

Includes amendments: F2024L01524

This compilation is in 10 volumes

Volume 1: sections 1–24 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: C4076–C9993)
Volume 6: Schedule 4 (Part 1: C10020–C12999)
Volume 7: Schedule 4 (Part 1: C13006–C13925)
Volume 8: Schedule 4 (Part 1: C13927–C14567)
Volume 9: Schedule 4 (Part 1: C14568–C16223, Part 2)
Volume 10: Schedules 5, 6 and Endnotes

Each volume has its own contents

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About this compilation

This compilation

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

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

Uncommenced amendments

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

Application, saving and transitional provisions for provisions and amendments

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

Editorial changes

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

Modifications

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

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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Schedule 4—Circumstances, purposes, conditions and variations

Note: See sections 13, 15, 16, 19 and 23.

Part 1—Circumstances, purposes and conditions

1 Circumstances, purposes and conditions

The following table sets out:

(a) circumstances for circumstances codes, for the purposes of section 13 and 23; and

(b) purposes for purposes codes, for the purposes of sections 15 and 16; and

(c) for the purposes of section 19, information relating to how authorisation is obtained when the circumstances or conditions for writing a prescription include an authorisation requirement.

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13927	P13927	CN13927	Ustekinumab	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)]; 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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must not exceed a single dose to be administered at week 8 under this restriction; Patient must be at least 18 years of age. 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 completed current Mayo clinic or partial Mayo clinic 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. 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. An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy. 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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				under a new cycle under the initial 3 treatment restriction. A maximum of 16 weeks of treatment with this drug will be approved under this criterion. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats. Details of the accepted toxicities including severity can be found on the Services Australia website.	
C13936	P13936	CN13936	Memantine	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 to 14 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;	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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.	
C13938	P13938	CN13938	Donepezil Galantamine Rivastigmine	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	P13940	CN13940	Donepezil Galantamine	Mild to moderately severe Alzheimer disease Initial Patient must have a baseline Mini-Mental State Examination (MMSE) or	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Rivastigmine	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.	
C13941	P13941	CN13941	Donepezil Galantamine Rivastigmine	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.	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C13945	P13945	CN13945	Abiraterone	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
C13946	P13946	CN13946	Ozanimod	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)]; AND 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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13948	P13948	CN13948	Pembrolizumab	Stage IV clear cell variant renal cell carcinoma (RCC) Initial treatment Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records; AND The condition must be untreated; AND Patient must have a WHO performance status of 2 or less; AND Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; or Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions. or Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	Compliance with Authority Required procedures - Streamlined Authority Code 13948
C13949	P13949	CN13949	Pembrolizumab	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 not have developed disease progression while receiving treatment with this drug for this condition; AND Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; or Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND Patient must be undergoing treatment with this drug administered once every 3	Compliance with Authority Required procedures - Streamlined Authority Code 13949

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				weeks - prescribe up to 6 repeat prescriptions; or Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.	
C13950	P13950	CN13950	Asciminib	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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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).	
C13952	P13952	CN13952	Ustekinumab	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)]; AND Patient must have received insufficient therapy with this drug for this condition under	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C13955	P13955	CN13955	Ustekinumab	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)]; AND 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; 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); AND The treatment must not exceed a single dose to be administered at week 8 under this restriction; Patient must be at least 18 years of age. 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 completed current Mayo clinic or partial Mayo clinic 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.	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 or partial Mayo clinic score must be no more than 4 weeks old at the time of application. 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. An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy. 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 maximum of 16 weeks of treatment with this drug will be approved under this criterion. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats. Details of the accepted toxicities including severity can be found on the Services Australia website.	
C13958	P13958	CN13958	Upadacitinib	Moderate to severe ulcerative colitis Continuing treatment - balance of supply	Compliance with Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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)]; AND The treatment must have been prescribed most recently through the Continuing treatment phase in a quantity which did not seek the full number available in regards to any of: (i) the quantity per dispensing, (ii) repeat prescriptions; AND The treatment must provide no more than the balance of 24 weeks treatment.	procedures
C13959	P13959	CN13959	Upadacitinib	Moderate to severe ulcerative colitis Dose modification 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)]; AND Patient must be undergoing existing PBS-subsidised treatment with this therapy.	Compliance with Authority Required procedures
C13966	P13966	CN13966	Memantine	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.	Compliance with Authority Required procedures - Streamlined Authority Code 13966

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C13967	P13967	CN13967	Naltrexone	Alcohol dependence The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence/controlled consumption.	Compliance with Authority Required procedures - Streamlined Authority Code 13967
C13972	P13972	CN13972	Lenvatinib	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 not have developed disease progression while receiving treatment with this drug for this condition; AND Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib. or Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records. or Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose. In a patient who has experienced an intolerance to pembrolizumab, details of intolerance must be documented in the patient's medical record.	Compliance with Authority Required procedures - Streamlined Authority Code 13972

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13977	P13977	CN13977	Vosoritide	Achondroplasia Initial treatment Patient must have a diagnosis of achondroplasia, confirmed by appropriate genetic testing; AND Patient must not have evidence of growth plate closure demonstrated by at least one of the following: i) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 6 months of this application if puberty has commenced; ii) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 2 years of commencing treatment if puberty has not commenced; iii) an annual growth velocity of greater than 1.5 cm/year as assessed over a period of at least 6 months; AND Must be treated by a medical specialist, experienced in the management of achondroplasia. or Must be treated by a paediatrician in consultation with a medical specialist experienced in the management of achondroplasia. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised. Appropriate genetic testing constitutes testing for FGFR3 gene mutation. In patients where puberty has not commenced, radiographic evidence that epiphyses have not closed must be obtained within 2 years of commencing treatment with vosoritide. X-rays and dates (date commenced treatment and date of X-ray) must be documented in the patient's medical records. Additional radiographic evidence is not required until patient has begun puberty. In patients where puberty has commenced, radiographic evidence that epiphyses have not closed must be obtained within 6 months of completing an authority application for vosoritide. X-ray and date taken must be documented in the patient's medical records.	Compliance with Authority Required procedures
C13988	P13988	CN13988	Ustekinumab	Moderate to severe ulcerative colitis	Compliance with

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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)]; AND 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 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; 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); AND The treatment must not exceed a single dose to be administered at week 8 under this restriction; Patient must be at least 18 years of age. 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	Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(i) the completed current Mayo clinic or partial Mayo clinic 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 or partial Mayo clinic score 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 between 8 and 16 weeks of therapy. 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. 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. 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. A maximum of 16 weeks of treatment with this drug will be approved under this criterion. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				90 mg and no repeats.	
C13990	P13990	CN13990	Upadacitinib	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)]; AND 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; 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); Patient must be at least 18 years of age. 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 completed current Mayo clinic or partial Mayo clinic 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. The most recent Mayo clinic or partial Mayo clinic score 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 between 8 and 16 weeks of therapy.	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. 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 maximum of 16 weeks of treatment with this drug will be approved under this criterion.	
C13992	P13992	CN13992	Abiraterone and methylprednisolone	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
C13995	P13995	CN13995	Ozanimod	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)]; AND Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 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; 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); Patient must be at least 18 years of age. 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 completed current Mayo clinic or partial Mayo clinic 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 or partial Mayo clinic score must be no more than 4 weeks old at the time of application.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy. 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. 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. 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. A maximum of 16 weeks of treatment with this drug will be approved under this criterion.	
C13998	P13998	CN13998	Vosoritide	Achondroplasia Continuing treatment Patient must have received PBS subsidised vosoritide treatment for this condition; AND Patient must not have evidence of growth plate closure demonstrated by at least one of the following: i) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 6 months of this application if puberty has commenced; ii) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 2 years of commencing treatment if puberty has not commenced; iii) an annual growth velocity of greater than 1.5 cm/year as assessed over a period of at least 6 months; AND Must be treated by a medical specialist, experienced in the management of achondroplasia. or Must be treated by a paediatrician in consultation with a medical specialist	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				experienced in the management of achondroplasia. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised. In patients where puberty has not commenced, radiographic evidence that epiphyses have not closed must be obtained within 2 years of commencing treatment with vosoritide. X-rays and dates (date commenced treatment and date of X-ray) must be documented in the patient's medical records. Additional radiographic evidence is not required until patient has begun puberty. In patients where puberty has commenced, radiographic evidence that epiphyses have not closed must be obtained within 6 months of completing an authority application for vosoritide. X-ray and date taken must be documented in the patient's medical records.	
C13999	P13999	CN13999	Upadacitinib	Moderate to severe ulcerative colitis Initial treatment - Initial 1 (new patient - untreated with biological medicine) 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)]; AND 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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 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; 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); Patient must be at least 18 years of age. 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 completed current Mayo clinic or partial Mayo clinic 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 or partial Mayo clinic score 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 between 8 and 16 weeks of therapy. 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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. 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. 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. A maximum of 16 weeks of treatment with this drug will be approved under this criterion.	
C14000	P14000	CN14000	Memantine	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 to 14; 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 of 10 to 14. 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
C14001	P14001	CN14001	Nivolumab	Stage IV clear cell variant renal cell carcinoma (RCC) Induction treatment The condition must not have previously been treated; AND Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records; AND Patient must have a WHO performance status of 2 or less; AND	Compliance with Authority Required procedures - Streamlined Authority Code 14001

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition. Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	
C14002	P14002	CN14002	Ozanimod	Moderate to severe ulcerative colitis 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)]; AND 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; Patient must be at least 18 years of age. Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 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. 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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14003	P14003	CN14003	Ozanimod	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)]; 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; Patient must be at least 18 years of age. 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 completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(ii) the details of prior biological medicine treatment including the details of date and duration of treatment. An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy. 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. A maximum of 16 weeks of treatment with this drug will be approved under this criterion.	
C14004	P14004	CN14004	Ozanimod	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)]; AND 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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				approved PBS-subsidised biological medicine for this condition; AND Patient must have a Mayo clinic score greater than or equal to 6; 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); Patient must be at least 18 years of age. 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 completed current Mayo clinic or partial Mayo clinic 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. The most recent Mayo clinic or partial Mayo clinic score 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 between 9 and 17 weeks of therapy. 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 maximum of 16 weeks of treatment with this drug will be approved under this criterion.	
C14005	P14005	CN14005	Ozanimod	Moderate to severe ulcerative colitis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a	Compliance with Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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)]; AND 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.	procedures
C14008	P14008	CN14008	Asciminib	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.	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	
C14011	P14011	CN14011	Upadacitinib	Moderate to severe ulcerative colitis 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)]; AND 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; Patient must be at least 18 years of age.	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 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. 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.	
C14014	P14014	CN14014	Upadacitinib	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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				gastroenterology (code 82)]; 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; Patient must be at least 18 years of age. 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 completed current Mayo clinic or partial Mayo clinic 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. An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy. 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. A maximum of 16 weeks of treatment with this drug will be approved under this	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				criterion.	
C14015	P14015	CN14015	Daratumumab	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; AND 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 Authority Required procedures
C14017	P14017	CN14017	Ozanimod	Moderate to severe ulcerative colitis Dose escalation occurring at initial treatment or re-initiation of treatment Must be treated by a gastroenterologist (code 87). or Must be treated by a consultant physician [internal medicine specialising in	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				gastroenterology (code 81)]. or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].	Code 14017
C14018	P14018	CN14018	Ustekinumab	Moderate to severe ulcerative colitis 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)]; 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 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; AND Patient must not receive more than 24 weeks of treatment under this restriction; Patient must be at least 18 years of age. Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 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. 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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C14021	P14021	CN14021	Selinexor	Relapsed and/or refractory multiple myeloma Initial treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week The condition must be confirmed by a histological diagnosis; AND Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; or Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) 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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14022	P14022	CN14022	Selinexor	Relapsed and/or refractory multiple myeloma Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 80 mg, 60 mg or 40 mg per week Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023; 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: (a) the condition was confirmed by histological diagnosis, (b) the treatment is/was being used as part of combination therapy limited to this drug in combination with either: (i) dexamethasone, (ii) dexamethasone plus bortezomib, (c) the condition progressed (see definition of progressive disease below) after at least one prior therapy, (d) 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.	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14023	P14023	CN14023	Selinexor	Relapsed and/or refractory multiple myeloma Continuing treatment - Dose requirement of 100 mg per week Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; or Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) 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
C14024	P14024	CN14024	Selinexor	Relapsed and/or refractory multiple myeloma Initial treatment - Dose requirement of 100 mg per week The condition must be confirmed by a histological diagnosis; AND	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; or Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) 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. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy	
C14026	P14026	CN14026	Ciclosporin	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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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; AND 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).	
C14027	P14027	CN14027	Pembrolizumab	Advanced, metastatic or recurrent endometrial carcinoma Initial treatment Patient must have received prior treatment with platinum-based chemotherapy; AND The condition must be untreated with each of: (i) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (ii) tyrosine kinase inhibitor therapy; 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 be undergoing combination therapy consisting of:	Compliance with Authority Required procedures - Streamlined Authority Code 14027

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(i) pembrolizumab, (ii) lenvatinib; or Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions. or Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	
C14031	P14031	CN14031	Selinexor	Relapsed and/or refractory multiple myeloma Continuing treatment - Dose requirement of 160 mg per week Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) 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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14032	P14032	CN14032	Ciclosporin	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; 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. 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). (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). State in all continuing treatment authority applications (ii) the ocular surface disease index score at the time of this authority application (a numerical value that is at least 30% lower than that stated in the first Initial 1	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				treatment authority application).	
C14034	P14034	CN14034	Abiraterone and methylprednisolone Apalutamide Darolutamide Enzalutamide	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; AND Patient must be undergoing concurrent androgen deprivation therapy.	Compliance with Authority Required procedures
C14037	P14037	CN14037	Selinexor	Relapsed and/or refractory multiple myeloma Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 100 mg per week Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023; 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: (a) the condition was confirmed by histological diagnosis, (b) the treatment is/was being used as part of combination therapy limited to this drug in combination with either: (i) dexamethasone, (ii) dexamethasone plus bortezomib, (c) the condition progressed (see definition of progressive disease below) after at least one prior therapy, (d) 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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	
C14039	P14039	CN14039	Selinexor	Relapsed and/or refractory multiple myeloma Initial treatment - Dose requirement of 160 mg per week The condition must be confirmed by a histological diagnosis; AND Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) 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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy	
C14040	P14040	CN14040	Nicotine	Nicotine dependence The treatment must be as an aid to achieving abstinence from smoking; AND The treatment must not be a PBS-benefit with other non-nicotine drugs that are PBS indicated for smoking cessation; AND Patient must have indicated they are ready to cease smoking; AND Patient must not receive more than 2 x 12-week PBS-subsidised treatment courses per 12 month period; AND 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.	
C14041	P14041	CN14041	Lenvatinib	Advanced, metastatic or recurrent endometrial carcinoma 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 receiving PBS-subsidised treatment with this drug for this condition; AND Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib. or Patient must be undergoing monotherapy with this drug due to a	Compliance with Authority Required procedures - Streamlined Authority Code 14041

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records. or Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose.	
C14042	P14042	CN14042	Lenvatinib	Advanced, metastatic or recurrent endometrial carcinoma Initial treatment Patient must have received prior treatment with platinum-based chemotherapy; AND The condition must be untreated with each of: (i) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (ii) tyrosine kinase inhibitor therapy; 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 be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib. or Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 14042
C14044	P14044	CN14044	Pembrolizumab	Advanced, metastatic or recurrent endometrial carcinoma 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 receiving PBS-subsidised treatment with this drug for this condition; AND Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; or Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's	Compliance with Authority Required procedures - Streamlined Authority Code 14044

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				medical records; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; or Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.	
C14045	P14045	CN14045	Selinexor	Relapsed and/or refractory multiple myeloma Continuing treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; or Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) 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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14047	P14047	CN14047	Cannabidiol	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; AND 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
C14061	P14061	CN14061	Adalimumab	Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) Must be treated by a paediatric rheumatologist; or	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; 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. 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. At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised. 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 details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. 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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 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 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.	
C14063	P14063	CN14063	Adalimumab	Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) Must be treated by a paediatric rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND 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 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition; 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. 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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 and must be documented in the patient's medical records. 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 active joints, the response must be demonstrated on the total number of active joints. At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records (a) the date of assessment of severe active juvenile idiopathic; and (b) the date of the last continuing prescription. 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 details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. 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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14064	P14064	CN14064	Adalimumab	Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a paediatric rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; or Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be under 18 years of age. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records. If intolerance to treatment develops during the relevant period of use, which is of a	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application (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 assessment of response to prior treatment must be documented in the patient's medical records. The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records (a) the date of assessment of severe active juvenile idiopathic arthritis; and (b) details of prior treatment including dose and duration of treatment. At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised. 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. 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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C14068	P14068	CN14068	Etanercept	Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) Must be treated by a paediatric rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; 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. 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. 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 3 repeats will be authorised. 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 details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				timeframes specified below. 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 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 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed 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.	
C14070	P14070	CN14070	Etanercept	Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a paediatric rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; or Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be under 18 years of age. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records. 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 documented in the patient's medical records. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application (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 assessment of response to prior treatment must be documented in the patient's medical records.	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records (a) the date of assessment of severe active juvenile idiopathic arthritis; and (b) details of prior treatment including dose and duration of treatment. 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 3 repeats will be authorised. 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. 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.	
C14071	P14071	CN14071	Etanercept	Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) Must be treated by a paediatric rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND 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 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. 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 and must be documented in the patient's medical records. 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 active joints, the response must be demonstrated on the total number of active joints. 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 3 repeats will be authorised. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records (a) the date of assessment of severe active juvenile idiopathic arthritis; and (b) the date of the last continuing prescription. 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 details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. 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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14080	P14080	CN14080	Tocilizumab	Systemic juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient weighing at least 30 kg) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; or Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be under 18 years of age; Must be treated by a rheumatologist. or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application (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, 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 prior treatment must be documented in the patient's	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				medical records. The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN). The assessment of response to prior treatment must be documented in the patient's medical records. The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. 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. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records. 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 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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 information must be provided by the prescriber at the time of application and documented in the patient's medical records (a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and (b) details of prior treatment including dose and duration of treatment. The following reports must be documented in the patient's medical records where appropriate (a) the date of assessment of severe active systemic juvenile idiopathic arthritis; (b) details of prior treatment including dose and duration of treatment; and (c) the pathology reports detailing CRP and platelet count where appropriate.	
C14084	P14084	CN14084	Tocilizumab	Systemic juvenile idiopathic arthritis Continuing treatment in a patient weighing less than 30 kg 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; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Must be treated by a rheumatologist. or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. An adequate response to treatment is defined as (a) in a patient with polyarticular course disease (i) 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 (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50% (b) in a patient with refractory systemic symptoms (i) absence of fever greater than 38 degrees Celsius in the preceding seven days;	Compliance with Authority Required procedures - Streamlined Authority Code 14084

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				and/or (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dose of corticosteroid by at least 30% from baseline. - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or - 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). (b) in a patient with refractory systemic symptoms (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dose of corticosteroid by at least 30% from baseline. 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 measurements of disease severity provided with the initial treatment application. The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records. 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. 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.	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring 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 prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C14088	P14088	CN14088	Tocilizumab	Systemic juvenile idiopathic arthritis Continuing treatment in a patient weighing at least 30 kg 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; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Must be treated by a rheumatologist. or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. An adequate response to treatment is defined as (a) in a patient with polyarticular course disease (i) 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 (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50% (b) in a patient with refractory systemic symptoms (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dose of corticosteroid by at least 30% from baseline. - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or	Compliance with Authority Required procedures - Streamlined Authority Code 14088

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				- 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). (b) in a patient with refractory systemic symptoms (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dose of corticosteroid by at least 30% from baseline. 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 measurements of disease severity provided with the initial treatment application. The following reports must be documented in the patient's medical records where appropriate (a) baseline and current pathology reports detailing C-reactive protein (CRP) levels; and (b) baseline and current pathology reports detailing platelet count. The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records. 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. 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.	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring 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 prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C14094	P14094	CN14094	Tocilizumab	Systemic juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient weighing less than 30 kg) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; or Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be under 18 years of age; Must be treated by a rheumatologist. or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application (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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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 prior treatment must be documented in the patient's medical records. The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN). The assessment of response to prior treatment must be documented in the patient's medical records. The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. 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. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 documented in the patient's medical records. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records (a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and (b) the details of prior treatment including dose and duration of treatment. The following reports must be documented in the patient's medical records where appropriate (a) pathology reports detailing C-reactive protein (CRP) level and platelet count. 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.	
C14096	P14096	CN14096	Choriogonadotropin alfa	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.	
C14097	P14097	CN14097	Finerenone	Chronic kidney disease with Type 2 diabetes 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	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				initiating treatment with this drug; AND Patient must not have known significant non-diabetic renal disease, prior to initiating treatment with this drug; AND Patient must have an estimated glomerular filtration rate of 25 mL/min/1.73 m^2 or greater, prior to initiating treatment with this drug; AND Patient must have a urinary albumin-to-creatinine ratio of 200 mg/g (22.6 mg/mmol) or greater, 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 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; AND The treatment must be in combination with an SGLT2i unless medically contraindicated or intolerant; AND Patient must not be receiving treatment with another selective nonsteroidal mineralocorticoid receptor antagonist, a renin inhibitor or a potassium-sparing diuretic; AND Patient must not have established heart failure with reduced ejection fraction with an indication for treatment with a mineralocorticoid receptor antagonist.	Code 14097
C14103	P14103	CN14103	Tocilizumab	Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a paediatric rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; or Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; Patient must be under 18 years of age. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records. 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 documented in the patient's medical records. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application (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 assessment of response to prior treatment must be documented in the patient's medical records. The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				treatment. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records (a) the date of assessment of severe active juvenile idiopathic arthritis; and (b) details of prior treatment including dose and duration of treatment. Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction. 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. 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.	
C14104	P14104	CN14104	Tocilizumab	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; 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 demonstrated an adequate response to treatment with this drug; AND Patient must be under 30kg; 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%	Compliance with Authority Required procedures - Streamlined Authority Code 14104

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14107	P14107	CN14107	Adalimumab	Severe active juvenile idiopathic arthritis Continuing treatment	Compliance with Authority Required procedures -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; 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 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	Streamlined Authority Code 14107

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14121	P14121	CN14121	Tocilizumab	Systemic juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of a new treatment cycle after a break of more than 12 months in a patient weighing less than 30 kg) Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have had a break in treatment of 12 months or more from this drug for this condition; AND Patient must have polyarticular course disease and the condition must have at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (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); (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); or Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN); AND Patient must not receive more than 16 weeks of treatment under this restriction; AND Must be treated by a rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre;	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be under 18 years of age. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records (a) the date of assessment of severe active systemic juvenile idiopathic arthritis. The following reports must be documented in the patient's medical records where appropriate (a) pathology reports detailing C-reactive protein (CRP) level and platelet count. The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application. 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 details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. 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 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.	
C14124	P14124	CN14124	Choriogonadotropin alfa	Assisted Reproductive Technology Patient must be receiving 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.	Compliance with Authority Required procedures - Streamlined Authority Code 14124
C14136	P14136	CN14136	Adalimumab	Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; or	Compliance with Authority Required procedures - Streamlined Authority

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; 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 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.	Code 14136

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14147	P14147	CN14147	Tocilizumab	Systemic juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months in a patient weighing at least 30 kg) Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have had a break in treatment of 12 months or more from this drug for this condition; AND Patient must have polyarticular course disease and the condition must have at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (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); (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); or Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN); AND Patient must not receive more than 16 weeks of treatment under this restriction; AND Must be treated by a rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; Patient must be under 18 years of age. The following information must be provided by the prescriber at the time of	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				application and documented in the patient's medical records (a) the date of assessment of severe active systemic juvenile idiopathic arthritis. The following reports must be documented in the patient's medical records where appropriate (a) pathology reports detailing C-reactive protein (CRP) level and platelet count. The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application. 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 details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. 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 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.	
C14150	P14150	CN14150	Tocilizumab	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; 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 demonstrated an adequate response to treatment with this drug; AND Patient must be 30kg or over; AND Patient must not receive more than 24 weeks of treatment per continuing treatment	Compliance with Authority Required procedures - Streamlined Authority Code 14150

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14153	P14153	CN14153	Tocilizumab	Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) Must be treated by a paediatric rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND 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 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition; 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. 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 and must be documented in the patient's medical records. 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 active joints, the response must be demonstrated on the total number of active joints. Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records (a) the date of assessment of severe active juvenile idiopathic arthritis; and (b) the date of the last continuing prescription.	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. 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.	
C14154	P14154	CN14154	Etanercept	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; 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 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	Compliance with Authority Required procedures - Streamlined Authority Code 14154

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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.	
C14155	P14155	CN14155	Etanercept	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	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				rheumatology treatment centre; 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 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	Code 14155

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14166	P14166	CN14166	Tocilizumab	Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) Must be treated by a paediatric rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; 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. 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.	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction. 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 details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. 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 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 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.	
C14175	P14175	CN14175	Tocilizumab	Systemic juvenile idiopathic arthritis Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months in a patient weighing at least 30 kg) Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				treatment with this drug more than once during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be under 18 years of age; Must be treated by a rheumatologist. or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. An adequate response to treatment is defined as (a) in a patient with polyarticular course disease (i) 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 (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50% (b) in a patient with refractory systemic symptoms (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dose of corticosteroid by at least 30% from baseline. - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or - 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). (b) in a patient with refractory systemic symptoms (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dose of corticosteroid by at least 30% from baseline. The assessment of response to treatment must be documented in the patient's medical records.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The following reports must be documented in the patient's medical records where appropriate (a) pathology reports detailing C-reactive protein (CRP) level and platelet count. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retrial or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. 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 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring 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 prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C14180	P14180	CN14180	Fluticasone propionate	Asthma The treatment must not be a PBS benefit where this 50 microgram strength is being initiated in a patient over the age of 6.00 years.	Compliance with Authority Required procedures - Streamlined Authority Code 14180
C14182	P14182	CN14182	Tocilizumab	Systemic juvenile idiopathic arthritis Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months in a patient weighing less than 30 kg) Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				treatment with this drug more than once during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be under 18 years of age; Must be treated by a rheumatologist. or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. An adequate response to treatment is defined as (a) in a patient with polyarticular course disease (i) 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 (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50% (b) in a patient with refractory systemic symptoms (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dose of corticosteroid by at least 30% from baseline. - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or - 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). (b) in a patient with refractory systemic symptoms (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dose of corticosteroid by at least 30% from baseline. The assessment of response to treatment must be documented in the patient's medical records.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The following reports must be documented in the patient's medical records where appropriate (a) pathology reports detailing C-reactive protein (CRP) level and platelet count. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retrial or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. 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 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring 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 prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C14195	P14195	CN14195	Tocilizumab	Active giant cell arteritis Initial treatment Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis; AND Patient must have clinical symptoms of active giant cell arteritis in the absence of any other identifiable cause; AND Patient must have an ESR equal to or greater than 30 mm/hour within the past 6 weeks; or Patient must have a CRP equal to or greater than 10 mg/L within the past 6 weeks; or Patient must have active giant cell arteritis confirmed by positive temporal artery	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				biopsy or imaging; AND Patient must have had a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis; AND Patient must have had temporal artery biopsy revealing features of giant cell arteritis at diagnosis; or Patient must have had evidence of large-vessel vasculitis by magnetic resonance (MR) or computed tomography (CT) angiography or PET/CT at diagnosis; or Patient must have had evidence of positive temporal artery halo sign by ultrasound (US) at diagnosis; AND The treatment must be in combination with a tapering course of corticosteroids; AND The treatment must not exceed 52 weeks in total including initial and continuing applications; Patient must be aged 50 years or older. Clinical symptoms of giant cell arteritis at diagnosis include unequivocal cranial symptoms of giant cell arteritis (new onset localized headache, scalp tenderness, temporal artery tenderness or decreased pulsation, ischemia related vision loss, or otherwise unexplained mouth or jaw pain upon mastication); or symptoms of polymyalgia rheumatica, defined as shoulder and/or hip girdle pain associated with inflammatory morning stiffness. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS and must include (a) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has active giant cell arteritis including pathology reports outlining the patient's ESR or CRP levels within the last 6 weeks, or positive temporal artery biopsy or imaging; and (b) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has been diagnosed with giant cell arteritis with a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis. 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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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).	
C14196	P14196	CN14196	Trabectedin	Advanced (unresectable and/or metastatic) leiomyosarcoma or liposarcoma Initial treatment Patient must have an ECOG performance status of 2 or less; AND Patient must have received prior chemotherapy treatment including an anthracycline; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must be one of the following subtypes for patients with liposarcoma: (i) dedifferentiated, (ii) myxoid, (iii) round-cell, (iv) pleomorphic. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.	Compliance with Authority Required procedures - Streamlined Authority Code 14196
C14197	P14197	CN14197	Trabectedin	Advanced (unresectable and/or metastatic) leiomyosarcoma or liposarcoma 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 receiving treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.	Compliance with Authority Required procedures - Streamlined Authority Code 14197
C14202	P14202	CN14202	Mifepristone and misoprostol	Termination of an intra-uterine pregnancy The condition must be an intra-uterine pregnancy of up to 63 days of gestation.	Compliance with Authority Required procedures - Streamlined Authority Code 14202
C14217	P14217	CN14217	Bimekizumab	Non-radiographic axial spondyloarthritis	Compliance with

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Upadacitinib	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 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; AND Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.	Authority Required procedures
C14228	P14228	CN14228	Calcium	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
C14229	P14229	CN14229	Mesalazine	Crohn disease The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C14231	P14231	CN14231	Calcitriol	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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14234	P14234	CN14234	Risedronic acid	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.	
C14235	P14235	CN14235	Risedronic acid	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.	
C14236	P14236	CN14236	Calcipotriol with betamethasone	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.	
C14238	P14238	CN14238	Acarbose Allopurinol Amlodipine	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Amlodipine with atorvastatin		
			Atenolol		
			Atorvastatin		
			Baclofen		
			Beclometasone		
			Betaxolol		
			Bimatoprost		
			Brimonidine		
			Brinzolamide		
			Budesonide		
			Candesartan		
			Carbamazepine		
			Carbimazole		
			Chlortalidone		
			Ciclesonide		
			Ciclosporin		
			Clonidine		
			Clopidogrel		
			Clopidogrel with aspirin		
			Colestyramine		
			Cortisone		

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Cyproterone		
			Dexamethasone		
			Diltiazem		
			Dorzolamide		
			Enalapril		
			Eprosartan		
			Estradiol		
			Estradiol and estradiol with dydrogesterone		
			Estradiol and estradiol with norethisterone		
			Estradiol with norethisterone		
			Estriol		
			Ethosuximide		
			Everolimus		
			Ezetimibe		
			Ezetimibe and rosuvastatin		
			Ezetimibe with atorvastatin		
			Ezetimibe with simvastatin		
			Felodipine		

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Fenofibrate		
			Fluticasone furoate		
			Fluticasone propionate		
			Fluvastatin		
			Furosemide		
			Gemfibrozil		
			Glibenclamide		
			Gliclazide		
			Glimepiride		
			Glipizide		
			Glyceryl trinitrate		
			Hydrochlorothiazide		
			Hydrochlorothiazide with amiloride		
			Hydrocortisone		
			Indapamide		
			Irbesartan		
			Isosorbide dinitrate		
			Isosorbide mononitrate		
			Labetalol		
			Latanoprost		
			Lercanidipine		

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Levodopa with benserazide		
			Levodopa with carbidopa		
			Lisinopril		
			Medroxyprogesterone		
			Metformin		
			Methenamine		
			Methotrexate		
			Metoprolol		
			Mycophenolic acid		
			Nicorandil		
			Nifedipine		
			Nizatidine		
			Norethisterone		
			Olmesartan		
			Pancreatic extract		
			Paraffin		
			Perindopril		
			Perindopril with indapamide		
			Phenytoin		
			Pilocarpine		

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Pizotifen		
			Potassium chloride		
			Potassium chloride with potassium bicarbonate		
			Pravastatin		
			Prazosin		
			Prednisolone		
			Prednisone		
			Probenecid		
			Propranolol		
			Propylthiouracil		
			Pyridostigmine		
			Ramipril		
			Rosuvastatin		
			Simvastatin		
			Sirolimus		
			Sodium bicarbonate		
			Spironolactone		
			Sulfasalazine		
			Sulthiame		
			Tacrolimus		
			Telmisartan		

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Toremifene		
			Trandolapril		
			Tranylcypromine		
			Travoprost		
			Valproic acid		
			Valsartan		
			Verapamil		
C14240	P14240	CN14240	Ticagrelor	Acute coronary syndrome (myocardial infarction or unstable angina) The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with aspirin.	Compliance with Authority Required procedures - Streamlined Authority Code 14240
C14242	P14242	CN14242	Alendronic acid	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.	
C14244	P14244	CN14244	Trandolapril with verapamil	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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must be inadequately controlled with verapamil.	
C14245	P14245	CN14245	Lercanidipine with enalapril Perindopril with amlodipine Ramipril with felodipine	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 dihydropyridine calcium channel blocker.	
C14246	P14246	CN14246	Perindopril with amlodipine	Stable coronary heart disease 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 therapy for coronary heart disease; AND The condition must be stabilised by treatment with perindopril and amlodipine at the same doses.	
C14251	P14251	CN14251	Bisoprolol Carvedilol Metoprolol succinate Nebivolol	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.	
C14254	P14254	CN14254	Sacubitril with valsartan	Chronic heart failure The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND 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 Patient must receive concomitant optimal standard chronic heart failure treatment, which must include a beta-blocker, unless at least one of the following is present in relation to the beta-blocker:	Compliance with Authority Required procedures - Streamlined Authority Code 14254

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(i) a contraindication listed in the Product Information, (ii) an existing/expected intolerance, (iii) local treatment guidelines recommend initiation of this drug product prior to a beta-blocker; AND Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; or Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist.	
C14255	P14255	CN14255	Candesartan with hydrochlorothiazide Irbesartan with hydrochlorothiazide Olmesartan with hydrochlorothiazide Telmisartan with hydrochlorothiazide Valsartan with hydrochlorothiazide	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.	
C14257	P14257	CN14257	Amlodipine with valsartan Olmesartan with amlodipine Telmisartan with amlodipine	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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14259	P14259	CN14259	Calcitriol	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
C14260	P14260	CN14260	Mesalazine	Ulcerative colitis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C14263	P14263	CN14263	Risedronic acid	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.	
C14264	P14264	CN14264	Apixaban Rivaroxaban	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	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have confirmed acute symptomatic deep vein thrombosis; AND Patient must not have symptomatic pulmonary embolism.	Code 14264
C14266	P14266	CN14266	Eplerenone	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
C14267	P14267	CN14267	Perindopril with indapamide	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-like diuretic.	
C14270	P14270	CN14270	Carvedilol	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.	
C14272	P14272	CN14272	Amlodipine with valsartan and hydrochlorothiazide Olmesartan with amlodipine and hydrochlorothiazide	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.	
C14274	P14274	CN14274	Raloxifene	Established post-menopausal osteoporosis The condition must be stable for the prescriber to consider the listed maximum	Compliance with Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	procedures - Streamlined Authority Code 14274
C14275	P14275	CN14275	Adapalene with benzoyl peroxide	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.	
C14280	P14280	CN14280	Enalapril with hydrochlorothiazide	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.	
C14287	P14287	CN14287	Calcitriol	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
C14289	P14289	CN14289	Moxonidine	Hypertension 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 receiving concurrent antihypertensive therapy.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14291	P14291	CN14291	Alendronic acid	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.	
C14296	P14296	CN14296	Calcitriol	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
C14298	P14298	CN14298	Rivaroxaban	Chronic stable atherosclerotic disease 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 received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with aspirin, but not with any other anti-platelet therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 14298
C14300	P14300	CN14300	Apixaban Rivaroxaban	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	Compliance with Authority Required procedures - Streamlined Authority

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have a history of venous thromboembolism.	Code 14300
C14301	P14301	CN14301	Apixaban Dabigatran etexilate Rivaroxaban	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 14301
C14305	P14305	CN14305	Atenolol	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.	
C14306	P14306	CN14306	Balsalazide	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
C14309	P14309	CN14309	Alendronic acid	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-	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14311	P14311	CN14311	Valsartan with hydrochlorothiazide	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.	
C14313	P14313	CN14313	Febuxostat	Chronic gout 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 either chronic gouty arthritis or chronic tophaceous gout; AND Patient must have a medical contraindication to allopurinol. or Patient must have a documented history of allopurinol hypersensitivity syndrome. or Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation.	Compliance with Authority Required procedures - Streamlined Authority Code 14313
C14318	P14318	CN14318	Apixaban Rivaroxaban	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 14318
C14319	P14319	CN14319	Thiamine	Thiamine deficiency 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 for prophylaxis; Patient must be an Aboriginal or a Torres Strait Islander person.	Compliance with Authority Required procedures - Streamlined Authority Code 14319
C14322	P14322	CN14322	Calcitriol	Hypocalcaemia	Compliance with

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be due to renal disease.	Authority Required procedures - Streamlined Authority Code 14322
C14323	P14323	CN14323	Azacitidine	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 Authority Required procedures
C14324	P14324	CN14324	Pembrolizumab	Recurrent, unresectable or metastatic triple negative breast cancer The condition must have been (up until this drug therapy) untreated in the unresectable/metastatic disease stage; AND The condition must have been (up until this drug therapy) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy in breast cancer; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative	Compliance with Authority Required procedures - Streamlined Authority Code 14324

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation; AND The treatment must be in combination with chemotherapy; AND The condition must have both: (i) programmed cell death ligand 1 (PD-L1) expression confirmed by a validated test, (ii) a Combined Positive Score (CPS) of at least 10 at treatment initiation; AND Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug; or Patient must be undergoing continuing treatment with this drug - both the following are true: (i) the condition has not progressed on active treatment with this drug, (ii) this prescription does not extend PBS subsidy beyond 24 cumulative months from the first administered dose; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions. or Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	
C14326	P14326	CN14326	Obinutuzumab	Chronic lymphocytic leukaemia (CLL) Combination use with chlorambucil only The condition must be CD20 positive; AND The condition must be previously untreated; AND The treatment must be in combination with chlorambucil; 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. Treatment must be discontinued in patients who experience disease progression whilst on this treatment.	Compliance with Authority Required procedures - Streamlined Authority Code 14326
C14327	P14327	CN14327	Patiromer	Chronic hyperkalaemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must not be in place of emergency treatment of hyperkalaemia; AND Patient must be undergoing treatment with a renin angiotensin aldosterone system inhibitor; AND Patient must not be undergoing dialysis.	Code 14327
C14332	P14332	CN14332	Azacitidine	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
C14337	P14337	CN14337	Zanubrutinib	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) First line drug treatment of this indication The condition must be untreated with drug treatment at the time of the first dose of this drug; or Patient must have developed an intolerance of a severity necessitating permanent	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL; AND The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug. or Patient must be undergoing continuing treatment with this drug - the condition has not progressed whilst the patient has actively been on this drug.	
C14338	P14338	CN14338	Azacitidine	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
C14340	P14340	CN14340	Venetoclax	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Initial treatment in first-line therapy - Dose titration (weeks 1 to 4 of a 5-week ramp-up schedule) The condition must be untreated with drug treatment at the time of the first dose of this drug; or Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL; AND The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses).	
C14342	P14342	CN14342	Patiromer	Chronic hyperkalaemia Initial PBS-subsidised treatment (including grandfathered patients) Patient must have stage 3 to stage 4 chronic kidney disease; The condition must be inadequately controlled by a low potassium diet.; AND Patient must have experienced at least 2 episodes of hyperkalaemia (defined as serum potassium levels of at least 6.0 mmol/L) within the 12 months prior to commencing this drug; AND The treatment must not be in place of emergency treatment of hyperkalaemia; AND Patient must be undergoing treatment with a renin angiotensin aldosterone system inhibitor; or Patient must be indicated for treatment with a renin angiotensin aldosterone system inhibitor, but unable to tolerate this due to prior occurrence of hyperkalaemia; AND Must be treated by a specialist medical practitioner with experience in the diagnosis and management of chronic kidney disease.	Compliance with Authority Required procedures
C14346	P14346	CN14346	Idelalisib	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Initial treatment The condition must be confirmed Chronic lymphocytic leukaemia (CLL) prior to initiation of treatment; or The condition must be confirmed Small lymphocytic lymphoma (SLL) prior to initiation of treatment; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with rituximab for up to a maximum of 8 doses under this restriction, followed by monotherapy for this condition; AND The condition must have relapsed or be refractory to at least one prior therapy; AND The condition must be CD20 positive; 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.	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14363	P14363	CN14363	Carfilzomib	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	P14364	CN14364	Carfilzomib	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	Compliance with Authority Required procedures - Streamlined Authority Code 14364

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14366	P14366	CN14366	Somatropin	Severe growth hormone deficiency Continuing treatment in a person with a mature skeleton or aged 18 years or older Must be treated by an endocrinologist; AND Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause in a patient with a mature skeleton. or Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to late onset of growth hormone deficiency secondary to organic hypothalamic or pituitary disease in a patient with chronological age of 18 years or older. or Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to late onset of growth	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				hormone deficiency diagnosed after skeletal maturity (bone age greater than or equal to 15.5 years in males or 13.5 years in females) and before chronological age of 18 years.	
C14374	P14374	CN14374	Bimekizumab	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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
C14375	P14375	CN14375	Bimekizumab	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.	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The most recent PASI assessment must be no more than 4 weeks old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C14376	P14376	CN14376	Bimekizumab	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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The 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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14377	P14377	CN14377	Adalimumab	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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14378	P14378	CN14378	Adalimumab	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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14382	P14382	CN14382	Etanercept	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.	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14387	P14387	CN14387	Fosnetupitant with palonosetron	Nausea and vomiting The treatment must be for prevention of nausea and vomiting associated with moderate to highly emetogenic anti-cancer therapy; AND The treatment must be in combination with dexamethasone, unless contraindicated; AND Patient must be unable to swallow. or Patient must be contraindicated to oral anti-emetics.	Compliance with Authority Required procedures
C14389	P14389	CN14389	Carfilzomib	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%	Compliance with Authority Required procedures - Streamlined Authority Code 14389

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14390	P14390	CN14390	Somatropin	Severe growth hormone deficiency Initial treatment of childhood onset growth hormone deficiency in a patient who has received non-PBS subsidised treatment as a child Must be treated by an endocrinologist; AND Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause; AND Patient must have previously received non-PBS subsidised treatment with this drug for this condition as a child; AND Patient must have current or historical evidence of an insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; or Patient must have current or historical evidence of an arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; or Patient must have current or historical evidence of a glucagon provocation test with maximum serum GH less than 3 micrograms per litre; Patient must have a mature skeleton.	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Somatropin is not PBS-subsidised for patients with Prader-Willi syndrome aged 18 years or older without a documented childhood onset Growth Hormone Deficiency. The authority application must be in writing and must include: A completed authority prescription form; AND A completed Severe Growth Hormone Deficiency supporting information form; AND Results of the growth hormone stimulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender.	
C14396	P14396	CN14396	Bimekizumab	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.	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				An application for a patient who has received PBS-subsidised treatment with this drug and 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 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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14398	P14398	CN14398	Adalimumab	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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14399	P14399	CN14399	Adalimumab	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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				this drug for this condition within this treatment cycle.	
C14400	P14400	CN14400	Guselkumab	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 20 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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 (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]. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. 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.	
C14403	P14403	CN14403	Pembrolizumab	Advanced carcinoma of the cervix Initial treatment The condition must be at least one of (i) persistent carcinoma, (ii) recurrent carcinoma, (iii) metastatic carcinoma of the cervix; AND The condition must be unsuitable for curative treatment with either of (i) surgical resection, (ii) radiation; AND Patient must have WHO performance status no higher than 1; AND Patient must not have received prior treatment for this PBS indication; AND Patient must be undergoing concomitant treatment with chemotherapy, containing a minimum of: (i) a platinum-based chemotherapy agent, plus (ii) paclitaxel; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions. or Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	Compliance with Authority Required procedures - Streamlined Authority Code 14403
C14404	P14404	CN14404	Pembrolizumab	Advanced carcinoma of the cervix Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed a total of (i) 24 months, (ii) 35 doses (based on a 3-	Compliance with Authority Required procedures - Streamlined Authority Code 14404

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				weekly dose regimen), (iii) 17 doses (based on a 6-weekly dose regimen) whichever comes first from the first dose of this drug regardless if it was PBS/non-PBS subsidised; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions. or Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	
C14415	P14415	CN14415	Ustekinumab	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 28 weeks of treatment under this restriction; Patient must be aged 18 years or older; Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin,	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised. 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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. 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.	
C14416	P14416	CN14416	Enfortumab vedotin	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; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND 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	Compliance with Authority Required procedures - Streamlined Authority Code 14416

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				following being true: (i) all other PBS eligibility criteria in this restriction are met, (ii) disease progression is absent.	
C14425	P14425	CN14425	Bimekizumab	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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
C14427	P14427	CN14427	Etanercept	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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
C14428	P14428	CN14428	Guselkumab	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 20 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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 (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]. 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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
C14430	P14430	CN14430	Secukinumab	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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 (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]. 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.	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14431	P14431	CN14431	Somatropin	Severe growth hormone deficiency Initial treatment of childhood onset growth hormone deficiency in a patient who has received PBS-subsidised treatment as a child Must be treated by an endocrinologist; AND Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition as a child; Patient must have a mature skeleton. Somatropin is not PBS-subsidised for patients with Prader-Willi syndrome aged 18 years or older without a documented childhood onset Growth Hormone Deficiency. The authority application must be in writing and must include: A completed authority prescription form; AND A completed Severe Growth Hormone Deficiency supporting information form.	Compliance with Written Authority Required procedures
C14437	P14437	CN14437	Bimekizumab	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,	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 recommence 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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14442	P14442	CN14442	Ustekinumab	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 28 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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 (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]. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised. 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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				this drug for this condition within this treatment cycle.	
C14443	P14443	CN14443	Netupitant with Palonosetron	Nausea and vomiting The treatment must be in combination with dexamethasone, unless contraindicated; AND The treatment must be for prevention of nausea and vomiting associated with moderate to highly emetogenic anti-cancer therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 14443
C14448	P14448	CN14448	Bimekizumab	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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
C14449	P14449	CN14449	Bimekizumab	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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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; AND Must be treated by a dermatologist.	
C14453	P14453	CN14453	Ixekizumab	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;	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application -	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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]. 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.	
C14460	P14460	CN14460	Bimekizumab	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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must not receive more than 24 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a 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.	
C14461	P14461	CN14461	Ixekizumab	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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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 (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]. 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.	
C14462	P14462	CN14462	Secukinumab	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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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,	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 (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]. 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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14464	P14464	CN14464	Tildrakizumab	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 28 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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 (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]. 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. At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.	
C14465	P14465	CN14465	Tildrakizumab	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 28 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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 (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]. 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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. 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. At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.	
C14471	P14471	CN14471	Dapagliflozin Empagliflozin	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
C14483	P14483	CN14483	Adalimumab	Severe active rheumatoid arthritis	Compliance with Written Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Baricitinib Etanercept Tocilizumab Tofacitinib Upadacitinib	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; AND 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	procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). 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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	
C14486	P14486	CN14486	Adalimumab Baricitinib Etanercept Tocilizumab Tofacitinib Upadacitinib	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; AND 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).	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14488	P14488	CN14488	Abatacept Adalimumab Baricitinib Etanercept Golimumab Tocilizumab Tofacitinib Upadacitinib	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; AND 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	CN14493	Adalimumab Baricitinib Certolizumab pegol Etanercept Tocilizumab Tofacitinib	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; 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 demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; Patient must be at least 18 years of age. An adequate response to treatment is defined as an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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-	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
C14496	P14496	CN14496	Adalimumab	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; AND 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	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The 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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				this drug for this condition.	
C14498	P14498	CN14498	Adalimumab Baricitinib Etanercept Tocilizumab Tofacitinib Upadacitinib	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; AND 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:	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
C14499	P14499	CN14499	Adalimumab Baricitinib Certolizumab pegol	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	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Etanercept Tocilizumab Tofacitinib Upadacitinib	rheumatoid arthritis; AND 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	Code 14499

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
C14507	P14507	CN14507	Abatacept Adalimumab Baricitinib Certolizumab pegol Etanercept Golimumab Infliximab Tocilizumab Tofacitinib	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; AND 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	CN14508	Etanercept	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; AND 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	Compliance with Authority Required procedures - Streamlined Authority Code 14508

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14509	P14509	CN14509	Etanercept	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; AND 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.	Compliance with Authority Required procedures - Streamlined Authority Code 14509

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14513	P14513	CN14513	Etanercept	Severe chronic plaque psoriasis Initial 1 treatment (Whole body) - biological medicine-naive patient Must be treated by a dermatologist; AND 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.	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. (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. 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.	
C14515	P14515	CN14515	Infliximab	Severe active rheumatoid arthritis Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must have received this drug (in any form) as their most recent course of	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; or Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; 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).	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.	
C14519	P14519	CN14519	Abatacept Golimumab	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; 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 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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
C14522	P14522	CN14522	Abatacept	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; AND 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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). 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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14542	P14542	CN14542	Certolizumab pegol	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; AND 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
C14543	P14543	CN14543	Ustekinumab	Severe chronic plaque psoriasis	Compliance with Written

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Initial 1 treatment (Whole body) - biological medicine-naive patient Must be treated by a dermatologist; AND 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 28 weeks of treatment 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 provided at the time of application. 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 provided at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website. 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 indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy	Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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. (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. A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of (i) the name of each prior therapy trialled that meets the above requirements - state at least 2; (ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies); (iii) the PASI score that followed each prior therapy trialled; (iv) the date the PASI scores were determined. Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.	
C14552	P14552	CN14552	Etanercept	Severe chronic plaque psoriasis Initial 2 treatment (Face, hand, foot) - Change of treatment Must be treated by a dermatologist; 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 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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. (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. In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because (i) there is an absence of an adequate response to that treatment; or (ii) there was an intolerance to that treatment; or (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above. The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.	
C14553	P14553	CN14553	Etanercept	Severe chronic plaque psoriasis Initial 4 - Re-treatment (Whole body) Must be treated by a dermatologist; AND 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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				whole body; AND 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; AND 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.	
C14554	P14554	CN14554	Etanercept	Severe chronic plaque psoriasis Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient Must be treated by a dermatologist; AND 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.	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 (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. (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. 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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. (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. 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.	
C14556	P14556	CN14556	Golimumab	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; AND 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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14557	P14557	CN14557	Golimumab	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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				rheumatoid arthritis; AND 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.	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. 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.	
C14558	P14558	CN14558	Ustekinumab	Severe chronic plaque psoriasis Continuing treatment (Whole body) - treatment covering week 28 and onwards Must be treated by a dermatologist; AND Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine; AND Patient must have demonstrated an adequate response to treatment; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. 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 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 provided in this application and 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.	
C14560	P14560	CN14560	Abatacept	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; AND 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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND 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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). 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.	
C14563	P14563	CN14563	Fremanezumab	Treatment-resistant migraine Continuing treatment Must be treated by a neurologist; or Must be treated by a general practitioner in consultation with 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; AND Patient must have previously received PBS-subsidised treatment with this drug for	Compliance with Authority Required procedures - Streamlined Authority Code 14563

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				this condition; AND Patient must have achieved and maintained at least 50% reduction from baseline in the number of migraine headache days per month; AND Patient must continue to be appropriately managed for medication overuse headache. Patient must have the number of migraine headache days per month documented in their medical records.	
C14567	P14567	CN14567	Adalimumab	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; 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 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	Compliance with Authority Required procedures - Streamlined Authority Code 14567

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	