National Health (Listing of Pharmaceutical Benefits) Instrument 2024

PB 26 of 2024

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National Health Act 1953

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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-I)
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-C14567)
Volume 8: Schedule 4 (Part 1: C14568-C16349)
Volume 9: Schedule 4 (Part 1: C16350-C17582, 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 November 2025 (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. The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. Any uncommenced amendments affecting the law are accessible on the Register (www.legislation.gov.au).

Application, saving and transitional provisions

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.

Presentational changes

The *Legislation Act 2003* provides for First Parliamentary Counsel to make presentational changes to a compilation. Presentational changes are applied to give a more consistent look and feel to legislation published on the Register, and enable the user to more easily navigate those documents.

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. Any modifications affecting the law are accessible on the Register.

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.

Contents

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)
C13006	P13006	CN13006	Ponatinib	Chronic Myeloid Leukaemia (CML) Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have maintained a major cytogenic response of less than 35% Philadelphia positive bone marrow cells at 12 month intervals. or Patient must have maintained a peripheral blood level of BCR-ABL of less than 1% on the international scale at 12 month intervals. A pathology report demonstrating the patient's cytogenetic response or a peripheral blood level of BCR-ABL must be documented in the patient's medical records.	Compliance with Authority Required procedures
C13007	P13007	CN13007	Lapatinib	Metastatic (Stage IV) HER2 positive breast cancer	Compliance with Written Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Initial treatment	procedures
				Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, confirmed through a pathology report from an Approved Pathology Authority; AND	
				The treatment must be in combination with capecitabine; AND	
				Patient must have received prior therapy with a taxane for at least 3 cycles; and experienced disease progression during or within 6 months of completing treatment with pertuzumab and trastuzumab in combination; or	
				Patient must have developed intolerance to treatment with a taxane of a severity necessitating permanent treatment withdrawal; and experienced disease progression during or within 6 months of completing treatment with pertuzumab and trastuzumab in combination; or	
				Patient must have experienced disease progression following treatment with trastuzumab emtansine in whom disease had relapsed during or within 6 months of completing prior adjuvant therapy with trastuzumab; or	
				Patient must have experienced disease relapsed during or within 6 months of completing prior adjuvant therapy with trastuzumab; AND	
				The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition; AND	
				The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.	
				Authority applications for initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include	
				(i) details (date, unique identifying number/code, or provider number) of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH); and	
				(ii) date of last treatment with a taxane and total number of cycles; or	
				(iii) dates of treatment with trastuzumab and pertuzumab; or	
				(iv) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab and pertuzumab; or	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(v) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. All reports must be documented in the patient's medical records. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval. If the application is submitted through HPOS upload or mail, it must include (a) a completed authority prescription form; and (b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
C13008	P13008	CN13008	Zanubrutinib	Waldenstrom macroglobulinaemia Initial treatment The condition must have relapsed or be refractory to at least one prior chemo-immunotherapy; or Patient must be unsuitable for treatment with chemo-immunotherapy, defined by a Cumulative Illness Rating Scale of 6 or greater, if untreated (i.e. treatment-naive) for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND Patient must be untreated with a Bruton's tyrosine kinase inhibitor for this condition. or Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this condition.	Compliance with Authority Required procedures
C13018	P13018	CN13018	Pertuzumab	Metastatic (Stage IV) HER2 positive breast cancer Initial treatment Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, confirmed through a pathology report from an Approved Pathology Authority; 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 have a WHO performance status of 0 or 1; AND Patient must not have received prior anti-HER2 therapy for this condition; AND Patient must not have received prior chemotherapy for this condition; AND The treatment must be in combination with trastuzumab and a taxane; AND The treatment must not be in combination with nab-paclitaxel; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Details (date, unique identifying number/code, or provider number) of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) must be provided at the time of application. The pathology report must be documented in the patient's medical records. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval.	
C13022	P13022	CN13022	Ponatinib	Chronic Myeloid Leukaemia (CML) First continuing treatment 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 have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals. or Patient must demonstrated a peripheral blood level of BCR-ABL of less than 1% on the international scale in the preceding 18 months and thereafter at 12 monthly intervals. The first 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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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).	
C13025	P13025	CN13025	Ponatinib	Chronic Myeloid Leukaemia (CML) Initial treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have failed an adequate trial of dasatinib confirmed through a pathology report from an Approved Pathology Authority; or Patient must have developed intolerance to dasatinib of a severity necessitating permanent treatment withdrawal; AND Patient must have failed an adequate trial of nilotinib confirmed through a pathology report from an Approved Pathology Authority. or Patient must have developed intolerance to nilotinib of a severity necessitating permanent treatment withdrawal. or Patient must not be eligible for PBS-subsidised treatment with nilotinib because the patient has a blast crisis. Failure of an adequate trial of dasatinib or nilotinib is defined as 1. Lack of response to dasatinib or nilotinib therapy, defined as either (i) failure to achieve a haematological response after a minimum of 3 months therapy with dasatinib or nilotinib; or (ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or (iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with dasatinib or nilotinib; OR 2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing	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)
				dasatinib or nilotinib 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 dasatinib or nilotinib therapy; OR 4. Development of accelerated phase or blast crisis in a patient previously prescribed dasatinib or nilotinib 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 dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia. Accelerated phase is defined by the presence of 1 or more of the following 1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or 2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or 3. Peripheral basophils greater than or equal to 20%; or 4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or 5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome). Blast crisis is defined as either 1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or 2. Extramedullary involvement other than spleen and liver. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include (i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or (ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				transcript greater than 0.1% on the international scale; and (iii) where there has been a loss of response to dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement. All reports must be documented in the patient's medical records If the application is submitted through HPOS form upload or mail, it must include (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Up to a maximum of 18 months of treatment may be authorised under this initial restriction.	
C13030	P13030	CN13030	Ponatinib	Chronic Myeloid Leukaemia (CML) Initial treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must be expressing the T315I mutation confirmed through a bone marrow biopsy pathology report; AND Patient must have failed an adequate trial of imatinib confirmed through a pathology report from an Approved Pathology Authority. or Patient must have failed an adequate trial of dasatinib confirmed through a pathology report from an Approved Pathology Authority. or Patient must have failed an adequate trial of nilotinib confirmed through a pathology report from an Approved Pathology Authority. Failure of an adequate trial of imatinib or dasatinib or nilotinib is defined as 1. Lack of response to imatinib or dasatinib or nilotinib therapy, defined as either (i) failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib or nilotinib; or (ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or (iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level	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)
				of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib or nilotinib; OR 2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib or nilotinib 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 imatinib or dasatinib or nilotinib therapy; OR 4. Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or dasatinib or nilotinib 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 imatinib or dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia. Accelerated phase is defined by the presence of 1 or more of the following 1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or 2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or 3. Peripheral basophils greater than or equal to 20%; or 4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or 5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome). Blast crisis is defined as either 1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or 2. Extramedullary involvement other than spleen and liver. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include (i) details (date, unique identifying number/code or provider number) of a bone marrow	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or (ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and (iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation; and (iv) where there has been a loss of response to imatinib or dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Up to a maximum of 18 months of treatment may be authorised under this initial restriction.	
C13039	P13039	CN13039	Infliximab	Complex refractory Fistulising Crohn disease Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine; AND Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved; 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	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)
				phase (the latest version is located on the website specified in the Administrative Advice). The PBS administrator will confirm that (i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient; (ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.	
C13040	P13040	CN13040	Infliximab	Severe psoriatic arthritis Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; or Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; Patient must be at least 18 years of age. Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.	Compliance with Authority Required procedures
C13045	P13045	CN13045	Infliximab	Moderate to severe ulcerative colitis Initial treatment with the subcutaneous form where a concurrent PBS authority	Compliance with Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				application for the intravenously (IV) administered formulation is being made Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine; AND Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved; 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). The PBS administrator will confirm that (i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient; (ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.	Required procedures
C13049	P13049	CN13049	Paliperidone	Schizophrenia Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months. or Patient must have previously received and be stabilised on PBS-subsidised paliperidone six-monthly injection for at least one cycle.	Compliance with Authority Required procedures - Streamlined Authority Code 13049
C13058	P13058	CN13058	Infliximab	Severe chronic plaque psoriasis Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription Must be treated by a dermatologist; AND Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat	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)
				prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; or Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; Patient must be at least 18 years of age. Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.	
C13069	P13069	CN13069	Infliximab	Severe active rheumatoid arthritis Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine; AND Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved; 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). The PBS administrator will confirm that (i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.	
C13077	P13077	CN13077	Infliximab	Ankylosing spondylitis Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine; AND Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved; 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). The PBS administrator will confirm that (i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient; (ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.	Compliance with Authority Required procedures
C13078	P13078	CN13078	Infliximab	Severe chronic plaque psoriasis Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine; AND Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/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)
				process of being approved; 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). The PBS administrator will confirm that (i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient; (ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.	
C13080	P13080	CN13080	Infliximab	Severe Crohn disease Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine; AND Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved; 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). The PBS administrator will confirm that (i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient; (ii) the concurrent authority application for the IV formulation is to be approved before	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				approving this authority application.	
C13082	P13082	CN13082	Paliperidone	Schizophrenia Patient must have previously received and be stabilised on PBS-subsidised paliperidone three-monthly injection for at least one cycle. or Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months.	Compliance with Authority Required procedures - Streamlined Authority Code 13082
C13094	P13094	CN13094	Infliximab	Complex refractory Fistulising Crohn disease Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription 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 continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; or Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; Patient must be at least 18 years of age. Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.	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)
C13096	P13096	CN13096	Infliximab	Ankylosing spondylitis Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis; AND Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; or Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; Patient must be at least 18 years of age. Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.	Compliance with Authority Required procedures
C13097	P13097	CN13097	Infliximab	Severe psoriatic arthritis Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine; AND Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				process of being approved; 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). The PBS administrator will confirm that (i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient; (ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.	
C13122	P13122	CN13122	Ciclosporin	Severe psoriasis Management (initiation, stabilisation and review of therapy) The condition must be ineffective to other systemic therapies; or The condition must be inappropriate for other systemic therapies; AND The condition must have caused significant interference with quality of life; AND Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist.	Compliance with Authority Required procedures - Streamlined Authority Code 13122
C13132	P13132	CN13132	Imatinib	Malignant gastrointestinal stromal tumour Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be given at a dose not exceeding 600 mg per day. Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses	Compliance with Authority Required procedures - Streamlined Authority Code 13132

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				higher than 600 mg per day will not be approved. A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347 472-80.)	
C13134	P13134	CN13134	Brentuximab vedotin	CD30 positive peripheral T-cell lymphoma, non-cutaneous type Initial treatment Patient must have histological confirmation of CD30 expression in at least 3% of malignant cells; AND The treatment must be for first line therapy for this condition; AND The treatment must be for curative intent; AND The treatment must be in combination with cyclophosphamide, doxorubicin and prednisone; AND The treatment must not be more than 6 treatment cycles under this restriction in a lifetime. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include (a) details (date, unique identifying number/code or provider number) of a histology report on the tumour sample from an Approved Pathology Authority showing CD30 positivity of at least 3% malignant cells; and (b) The date of initial diagnosis of Peripheral T-cell lymphoma. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Authority Required procedures
C13152	P13152	CN13152	Sunitinib	Metastatic or unresectable malignant gastrointestinal stromal tumour Initial treatment The condition must not be resectable; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				condition; AND Patient must have a WHO performance status of 2 or less; AND Patient must have previously failed or be intolerant to imatinib mesilate. Applications for authorisation 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). Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib.	
C13153	P13153	CN13153	Sunitinib	Metastatic or unresectable malignant gastrointestinal stromal tumour Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The condition must not be resectable; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must have a WHO performance status of 2 or less; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 13153
C13165	P13165	CN13165	Decitabine with cedazuridine	Chronic Myelomonocytic Leukaemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease. Up to 6 cycles will be authorised.	Compliance with Authority Required procedures
C13168	P13168	CN13168	Ciclosporin	Severe psoriasis Management (initiation, stabilisation and review of therapy)	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)
				The condition must be ineffective to other systemic therapies; or The condition must be inappropriate for other systemic therapies; AND The condition must have caused significant interference with quality of life; AND Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist.	Code 13168
C13175	P13175	CN13175	Sonidegib Vismodegib	Metastatic or locally advanced basal cell carcinoma (BCC) Initial treatment The condition must be inappropriate for surgery; AND The condition must be inappropriate for curative radiotherapy; AND Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; or Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal; AND Patient must not receive more than 16 weeks of treatment under this restriction. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include (a) Details (date, unique identifying number/code or provider number) of the histological confirmation of BCC and whether the condition is metastatic or locally advanced; and (b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that surgery is inappropriate; and (c) In patients with locally advanced BCC, written confirmation from a radiation oncologist that curative radiotherapy is inappropriate. The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria. 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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				phase (the latest version is located on the website specified in the Administrative Advice). **Inappropriate for surgery is defined as** (i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or (ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or (iii) Medical contraindication to surgery. (i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or (ii) Limitations due to location of tumour; or (iii) Limitations due to cumulative prior radiotherapy dose; or (iv) Progressive disease despite prior irradiation of locally advanced BCC. **Inappropriate for curative radiotherapy is defined as** (i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or (ii) Limitations due to location of tumour; or (iii) Limitations due to cumulative prior radiotherapy dose; or (iv) Progressive disease despite prior irradiation of locally advanced BCC. For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery and written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.	
C13177	P13177	CN13177	Vorinostat	Cutaneous T-cell lymphoma Initial treatment Patient must have received systemic treatment with chemotherapy; AND Patient must demonstrate relapsed or chemotherapy-refractory disease; AND Patient must be ineligible for stem cell transplant; AND The treatment must be the sole PBS-subsidised therapy for this condition. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include	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)
				(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).	
C13179	P13179	CN13179	Brentuximab vedotin	CD30 positive cutaneous T-cell lymphoma Initial treatment Patient must have pathologically confirmed CD30 positive cutaneous T-cell lymphoma; AND Patient must have CD30 positivity of at least 3% of malignant cells; AND Patient must have a diagnosis of mycosis fungoides; or Patient must have a diagnosis of Sezary syndrome; or Patient must have a diagnosis of primary cutaneous anaplastic large cell lymphoma; AND Patient must have received prior systemic treatment for this condition; AND The condition must be relapsed or refractory; AND The treatment must not exceed 4 cycles under this restriction in a lifetime; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include (a) details (date, unique identifying number/code or provider number) of the histopathology report from an Approved Pathology Authority demonstrating the patient has a diagnosis of either mycosis fungoides, Sezary syndrome or primary cutaneous anaplastic large cell lymphoma; and (b) details (date, unique identifying number/code or provider number) of a histology report on the tumour sample or of a flow cytometric analysis of lymphoma cells of the blood showing CD30 positivity of at least 3% of malignant cells; and (c) Date of commencement and completion of the most recent prior systemic treatment. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				phase (the latest version is located on the website specified in the Administrative Advice).	
C13181	P13181	CN13181	Brentuximab vedotin	CD30 positive cutaneous T-cell lymphoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have achieved an objective response with this drug; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The treatment must not exceed 12 cycles under this restriction in a lifetime. An objective response is defined as the demonstration of response by clinical observation of skin lesions, or response by positron-emission tomography (PET) and/or computed tomography (CT) standard criteria.	Compliance with Authority Required procedures
C13182	P13182	CN13182	Brentuximab vedotin	CD30 positive systemic anaplastic large cell lymphoma Initial treatment The treatment must be for curative intent; AND Patient must have undergone appropriate prior front-line curative intent chemotherapy; AND Patient must demonstrate relapsed or chemotherapy-refractory disease; AND Patient must have responded to PBS-subsidised treatment with this drug if previously used for initial treatment of CD30 positive peripheral T-cell lymphoma, non-cutaneous type; AND The treatment must not exceed 4 cycles under this restriction. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include (a) details (date, unique identifying number or provider number) of a histology report showing evidence of the tumour's CD30 positivity; and (b) The date of initial diagnosis of systemic anaplastic large cell lymphoma; and (c) Dates of commencement and completion of front-line curative intent chemotherapy;	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)
				and (d) a declaration of whether the patient's disease is relapsed or refractory, and the date and means by which the patient's disease was assessed as being relapsed or refractory. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
C13186	P13186	CN13186	Crizotinib Entrectinib	Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures
C13205	P13205	CN13205	Decitabine with cedazuridine	Chronic Myelomonocytic Leukaemia Initial treatment The condition must be chronic myelomonocytic leukaemia confirmed through a bone marrow biopsy report and full blood examination report; AND The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder. No more than 3 cycles will be authorised under this restriction in a patient's lifetime. The first authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include (a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has chronic myelomonocytic leukaemia; and (b) details (date, unique identifying number/code or provider number) of the full blood	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				examination report from an Approved Pathology Authority All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following reports must be documented in the patient's medical records (a) bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia; and (b) full blood examination report	
C13207	P13207	CN13207	Cabazitaxel	Castration resistant metastatic carcinoma of the prostate The treatment must be in combination with prednisone or prednisolone; AND The condition must be resistant to treatment with docetaxel; or Patient must have a documented intolerance necessitating permanent treatment withdrawal or a contraindication to docetaxel; AND The treatment must not be used in combination with a novel hormonal drug; AND Patient must have a WHO performance status of 2 or less; AND Patient must not receive PBS-subsidised cabazitaxel if progressive disease develops while on cabazitaxel.	Compliance with Authority Required procedures - Streamlined Authority Code 13207
C13212	P13212	CN13212	Brentuximab vedotin	CD30 positive peripheral T-cell lymphoma, non-cutaneous type Continuing treatment The treatment must be in combination with cyclophosphamide, doxorubicin and prednisone; AND Patient must have completed 6 initial cycles of PBS-subsidised treatment with this drug for this indication; AND Patient must have achieved at least a partial response to the 6 initial cycles of treatment with a combination of this drug and cyclophosphamide, doxorubicin and prednisone for this indication; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND	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 not be more than 2 treatment cycles under this restriction in a lifetime. Partial response is defined using Lugano Response Criteria for Non-Hodgkin Lymphoma as (a) Positron emission tomography-based response lymph nodes and extralymphatic sites - a score of 4 (uptake moderately > liver), or 5 (uptake markedly higher than liver and/or new lesions), with reduced uptake compared with baseline and residual mass(es) of any size; nonmeasured lesions - not applicable; organ enlargement - not applicable; new lesions - none; bone marrow - residual uptake higher than uptake in normal marrow but reduced compared with baseline (diffuse uptake compatible with reactive changes from chemotherapy allowed). If there are persistent focal changes in the marrow in the context of a nodal response, consideration should be given to further evaluation with MRI or biopsy or an interval scan; OR (b) Computed tomography-based response lymph nodes and extralymphatic sites - greater than or equal to 50% decrease in the sum of the product of the perpendicular diameters for multiple lesions, of up to six (6) target measurable nodes and extranodal sites; non-measured lesions - absent/normal, regressed but no increase; new lesions - none; bone marrow - not applicable.	
C13230	P13230	CN13230	Dapagliflozin	Chronic kidney disease Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug; AND Patient must have an estimated glomerular filtration rate of between 25 to 75 mL/min/1.73 m^2 inclusive prior to initiating treatment with this drug; AND Patient must have a urinary albumin to creatinine ratio of between 200 to 5000 mg/g (22.6-565 mg/mmol) inclusive prior to initiating treatment with this drug; AND Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant; AND Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug.	Compliance with Authority Required procedures - Streamlined Authority Code 13230

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patients with polycystic kidney disease, lupus nephritis or ANCA-associated vasculitis; patients requiring or with a recent history of cytotoxic or immunosuppressive therapy for kidney disease; and patients with an organ transplant are not eligible for treatment with this drug.	
C13236	P13236	CN13236	Vedolizumab	Severe Crohn disease Balance of supply - subcutaneous form 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 under the Initial treatment with subcutaneous form to complete 14 to 16 weeks Initial treatment (intravenous and subcutaneous inclusive); or Patient must have received insufficient therapy with this drug under the Continuing treatment to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form. or The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment - subcutaneous form.	Compliance with Authority Required procedures
C13237	P13237	CN13237	Vedolizumab	Moderate to severe ulcerative colitis Balance of supply - subcutaneous form 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 under the Initial treatment with subcutaneous form to complete 14 to 16 weeks Initial treatment (intravenous and subcutaneous inclusive); or Patient must have received insufficient therapy with this drug under the Continuing treatment to complete 24 weeks of treatment; 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 provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form. or The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment - subcutaneous form.	
C13241	P13241	CN13241	Decitabine with cedazuridine	Acute Myeloid Leukaemia Initial treatment The condition must be acute myeloid leukaemia confirmed through a bone marrow biopsy report and full blood examination; AND The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification. The following reports must be documented in the patient's medical records (a) bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and (b) full blood examination report.	Compliance with Authority Required procedures
C13246	P13246	CN13246	Vorinostat	Cutaneous T-cell lymphoma 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 The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures
C13257	P13257	CN13257	Decitabine with cedazuridine	Myelodysplastic syndrome Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease. Up to 6 cycles will be authorised.	Compliance with Authority Required procedures
C13258	P13258	CN13258	Decitabine with cedazuridine	Acute Myeloid Leukaemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this	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)
				condition; AND Patient must not have progressive disease.	Code 13258
C13260	P13260	CN13260	Sonidegib	Metastatic or locally advanced basal cell carcinoma (BCC) 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 The condition must remain inappropriate for surgery; AND The condition must remain inappropriate for curative radiotherapy; AND Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include (a) Confirmation from the treating doctor that the disease has not progressed; and (b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that the condition remains inappropriate for surgery; or written confirmation from a radiation oncologist that the condition remains inappropriate for curative radiotherapy. The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria. 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). **Inappropriate for surgery is defined as** (i) Curative resection is unlikely, such as where BCC has recurred in the same location	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)
				after two or more surgical procedures; or (ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or (iii) Medical contraindication to surgery. (i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or (ii) Limitations due to location of tumour; or (iii) Limitations due to cumulative prior radiotherapy dose; or (iv) Progressive disease despite prior irradiation of locally advanced BCC. **Inappropriate for curative radiotherapy is defined as** (i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or (ii) Limitations due to location of tumour; or (iii) Limitations due to cumulative prior radiotherapy dose; or (iv) Progressive disease despite prior irradiation of locally advanced BCC. For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery or written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.	
C13261	P13261	CN13261	Brentuximab vedotin	CD30 positive systemic anaplastic large cell lymphoma Continuing treatment Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed 12 cycles under this restriction in a lifetime.	Compliance with Authority Required procedures
C13267	P13267	CN13267	Decitabine with cedazuridine	Myelodysplastic syndrome Initial treatment The condition must be myelodysplastic syndrome confirmed through a bone marrow biopsy report and full blood examination; AND The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); or	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS); AND The condition must have up to 20% marrow blasts according to World Health Organisation (WHO) Classification. Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations (a) 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR (b) 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR (c) 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR (d) 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR (e) Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias. Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations (a) 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR (b) 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias. The following information must be provided by the prescriber at the time of application (a) The patient's International Prognostic Scoring System (IPSS) score. The following reports must be documented in the patient's medical records (a) bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and (b) full blood examination report; and (c) pathology report detailing the cytogenetics demonstrating intermediate-2 or high-risk disease according to the International Prognostic Scoring System (IPSS). No more than 3 cycles will be authorised under this restriction in a patient's lifetime.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13268	P13268	CN13268	Vismodegib	Metastatic or locally advanced basal cell carcinoma (BCC) 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 The condition must remain inappropriate for surgery; AND The condition must remain inappropriate for curative radiotherapy; AND Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include (a) Confirmation from the treating doctor that the disease has not progressed; and (b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that the condition remains inappropriate for surgery; or written confirmation from a radiation oncologist that the condition remains inappropriate for curative radiotherapy. The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria. 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). **Inappropriate for surgery is defined as** (i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or (ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or (iii) Medical contraindication to surgery. (i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or (ii) Limitations due to location of tumour; or (iii) Limitations due to cumulative prior radiotherapy dose; or (iv) Progressive disease despite prior irradiation of locally advanced BCC. **Inappropriate for curative radiotherapy is defined as** (i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or (ii) Limitations due to location of tumour; or (iii) Limitations due to cumulative prior radiotherapy dose; or (iv) Progressive disease despite prior irradiation of locally advanced BCC. For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery or written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.	
C13282	P13282	CN13282	Somatrogon	Short stature and slow growth Recommencement of treatment as a reclassified patient Patient must be undergoing treatment that is simultaneously: (a) recommencing treatment following a temporary break in treatment (i.e. a lapse), plus (b) reclassifying the PBS indication whilst continuing with the same growth hormone; subsidy through this treatment phase must not: (i) initiate treatment, (ii) change the prescribed drug, (iii) reclassify the PBS indication where the most recent authority approval was for a different growth hormone; AND Patient must have had a lapse in growth hormone treatment; AND The treatment must not be for the purposes of continuing treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information)	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)
				dose; AND	
				Patient must have had a height no higher than the 1st percentile for age plus sex at the time treatment first commenced; AND	
				Patient must have had a growth velocity below the 25th percentile for bone age plus sex measured over a 12 month interval (or a 6 month interval for an older child) prior to having commenced treatment; or	
				Patient must have had an annual growth velocity of no higher than 8 cm per year where the patient had either a bone/chronological age no higher than 2.5 years prior to having commenced treatment; AND	
				Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND	
				Patient must not have an active tumour or evidence of tumour growth or activity; AND	
				Patient must be male and must not have a height greater than or equal to 167.7 cm; or	
				Patient must be female and must not have a height greater than or equal to 155.0 cm; AND	
				Patient must be male and must not have a bone age of 15.5 years or more; or	
				Patient must be female and must not have a bone age of 13.5 years or more; AND	
				Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or	
				Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND	
				Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.	
				An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.	
				Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include	
				1. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				performed within the 12 months immediately prior to commencement of treatment where the patient had a chronological age greater than 2.5 years at commencement of treatment. 2. Recent growth data (height and weight, not older than three months). 3. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years. 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). Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction. Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C13284	P13284	CN13284	Somatrogon	Short stature and slow growth Initial treatment Patient must have a current height at or below the 1st percentile for age and sex; AND Patient must have a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less; AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND Patient must not have an active tumour or evidence of tumour growth or activity; AND Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; 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 male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND Patient must be male and must not have a height greater than or equal to 167.7 cm; or Patient must be female and must not have a height greater than or equal to 155.0 cm; AND Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; or Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm; AND Must be treated by a specialist or consultant physician in paediatric endocrinology; or Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology; AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: 1. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application. 2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years. 3. Confirmation of the patient's maturational or constitutional delay status. 4. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile. 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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Advice). Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction. Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C13287	P13287	CN13287	Somatrogon	Short stature associated with biochemical growth hormone deficiency Continuing treatment as a reclassified patient Patient must be undergoing continuing PBS-subsidised therapy with this drug where the most recent authority approval for this drug was for a different PBS indication to that stated above - subsidy through this treatment phase must not: (i) initiate treatment, (ii) change the prescribed drug, (iii) recommence treatment, (iv) reclassify the PBS indication where the most recent authority approval was for a different growth hormone, (v) reclassify the PBS indication and recommence treatment simultaneously; AND The treatment must not be for the purposes of continuing treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose; AND Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement	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)
				of treatment); or Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				plasma IGF-1 levels; or Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND Patient must not have an active tumour or evidence of tumour growth or activity; AND Patient must be male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years. Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include 1. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment where a patient had a chronological age greater than 2.5 years at commencement of treatment); OR (b) Height and weight measurements from within three months prior to commencement	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				of treatment for a patient whose height was at or below the 1st percentile for age plus sex immediately prior to commencing treatment. 2. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations. 3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months. 4. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years. 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). Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C13288	P13288	CN13288	Somatrogon	Short stature associated with biochemical growth hormone deficiency Change of drug Patient must be undergoing existing PBS-subsidised growth hormone treatment where the prescribed drug is changing within the same PBS indication - subsidy through this treatment phase must not: (i) initiate treatment, (ii) recommence treatment, (iii) reclassify the PBS indication; AND Patient must have been treated with PBS-subsidised growth hormone for less than 32 weeks; or Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) having been	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				demonstrated; or Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) not demonstrated due to at least one of: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance to treatment arising from social/family problems, (v) sub-optimal dosing (i.e. the dose was less than the permitted upper dose range); AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND Patient must not have an active tumour or evidence of tumour growth or activity; AND Patient must be male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND Must be treated by a specialist or consultant physician in paediatric endocrinology; or Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology; AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. Definition An adequate response to the preceding supply of growth hormone for which the patient is changing from is one where the patient, for their sex, has achieved at least one of (a) the 50th percentile growth velocity for bone age; (b) an increase in height standard deviation score for chronological age; (c) a minimum growth velocity of 4 cm per year; (d) a mid-parental height standard deviation score. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include 1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months. 2. A bone age result performed within the last 12 months where the patient has a	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				chronological age greater than 2.5 years. Where growth data has been supplied within 3 months of this authority application, do not resupply this data. 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). Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction. Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C13290	P13290	CN13290	Avelumab	Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer Maintenance therapy - Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 13290
C13292	P13292	CN13292	Somatrogon	Short stature associated with biochemical growth hormone deficiency Initial treatment Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND Patient must have a current height at or below the 1st percentile for age and sex; or Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less; or Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less; AND Patient must not have a condition with a known risk of malignancy including	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				chromosomal abnormalities such as Down and Bloom syndromes; AND Patient must not have an active tumour or evidence of tumour growth or activity; AND Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND Patient must be male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND Must be treated by a specialist or consultant physician in paediatric endocrinology; or Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology; AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: 1. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; or (b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex. 2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years. 3. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations. 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).	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction. Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C13293	P13293	CN13293	Mecasermin	Severe growth failure with primary insulin-like growth factor-1 deficiency Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have a bone age of less than 13.5 years (females); or Patient must have a bone age of less than 15.5 years (males); AND The treatment must not be in a patient with known epiphyseal closure/growth plate fusion (i.e. the patient is known to have ceased growing); AND The condition must be responsive to this drug treatment as evidenced by each of: (i) patient is showing catch-up for height standard deviation score against Laron syndrome (growth hormone insensitivity syndrome) growth charts, (ii) patient has a growth velocity of greater than 2 cm per year (extrapolated for time on treatment) at the time of this continuing authority application; or The condition must be yet to respond to this drug treatment only for the reason of sub-optimal dosing; AND Must be treated by a paediatric endocrinologist; the authority application must be completed by this physician type; or Must be treated by a paediatrician who has consulted the above mentioned specialist type; the authority application must be completed by this paediatrician; Patient must be aged from 2 years up until their 18th birthday. The continuing treatment authority application must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail	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)
				and must include (1) The patient's height (cm); (2) Where this authority application seeks to continue treatment where there has been an inadequate response to treatment due to sub-optimal dosing, state each of (i) the most recently prescribed dose (mg/kg) that resulted in an inadequate response; (ii) the dose (mg/kg) (between 0.04 to 0.12) that was/will be subsequently prescribed to address the inadequate response; (3) The patient's weight (kg); (4) The patient's growth velocity in response to the preceding supply of drug (cm/year; extrapolated for time on treatment); (5) The number of vials rounded to the nearest whole number, to provide sufficient drug quantity for 30 days of treatment per dispensing - see the relevant 'NOTE' attached to this listing for guidance. Height, growth velocity and weight measurements must not be more than three months old at the time of application. Document growth improvements 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).	
C13294	P13294	CN13294	Somatrogon	Short stature associated with biochemical growth hormone deficiency Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must be undergoing privately funded treatment (e.g. through a clinical trial, a sponsor compassionate access program, supply from an overseas jurisdiction) with this drug at the time of this authority application - subsidy through this treatment phase must only occur once per lifetime; AND The treatment must not be for the purposes of continuing treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				lower than recommended (as specified by this drug's approved Product Information) dose; AND Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND Patient must not have an active tumour or evidence of tumour growth or activity; AND Patient must be male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include 1. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment where a patient had a chronological age greater than 2.5 years at commencement of treatment); OR (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age plus sex immediately prior to commencing treatment. 2. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations. 3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months. 4. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years. 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). Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction. Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C13297	P13297	CN13297	Somatrogon	Short stature associated with biochemical growth hormone deficiency Recommencement of treatment	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 recommencing treatment following a temporary treatment break (i.e. a lapse) from this drug for the stated indication above - subsidy through this treatment phase must not: (i) initiate treatment, (ii) change the prescribed drug, (iii) reclassify the PBS indication; AND	
				Patient must have had a lapse in growth hormone treatment; AND	
				The treatment must not be for the purposes of resuming treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose; AND	
				Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND	
				Patient must not have an active tumour or evidence of tumour growth or activity; AND	
				Patient must be male and must not have a bone age of 15.5 years or more; or	
				Patient must be female and must not have a bone age of 13.5 years or more; AND	
				Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or	
				Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND	
				Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.	
				Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include	
				1. Recent growth data (height and weight, not older than three months).	
				2. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years.	
				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). Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction. Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C13298	P13298	CN13298	Somatrogon	Short stature associated with biochemical growth hormone deficiency Recommencement of treatment as a reclassified patient Patient must be undergoing treatment that is simultaneously: (a) recommencing treatment following a temporary break in treatment (i.e. a lapse), plus (b) reclassifying the PBS indication whilst continuing with the same growth hormone; subsidy through this treatment phase must not: (i) initiate treatment, (ii) change the prescribed drug, (iii) reclassify the PBS indication where the most recent authority approval was for a different growth hormone; AND Patient must have had a lapse in growth hormone treatment; AND The treatment must not be for the purposes of continuing treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose; AND Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval	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)
				immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND Patient must not have an active tumour or evidence of tumour growth or activity; AND Patient must be male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include 1. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment where a patient had a chronological age greater than 2.5 years at commencement of treatment); OR (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age plus	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				sex immediately prior to commencing treatment. 2. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations. 3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months. 4. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years. 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). Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction. Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C13304	P13304	CN13304	Somatrogon	Short stature and slow growth Recommencement of treatment Patient must be undergoing recommencing treatment following a temporary treatment break (i.e. a lapse) from this drug for the stated indication above - subsidy through this treatment phase must not: (i) initiate treatment, (ii) change the prescribed drug, (iii) reclassify the PBS indication; AND Patient must have had a lapse in growth hormone treatment; AND The treatment must not be for the purposes of resuming treatment that is known to be	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose; AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND Patient must not have an active tumour or evidence of tumour growth or activity; AND Patient must be male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND Patient must be male and must not have a height greater than or equal to 167.7cm; or Patient must be female and must not have a height greater than or equal to 155.0cm; AND Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include 1. Recent growth data (height and weight, not older than three months). 2. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years. 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). Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				'Notes' section of this restriction. Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C13308	P13308	CN13308	Somatrogon	Short stature and slow growth Continuing treatment Patient must be undergoing continuing PBS-subsidised therapy with this drug - subsidy through this treatment phase must not: (i) initiate treatment, (ii) change the prescribed drug, (iii) recommence treatment, (iv) reclassify the PBS indication; AND Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category; AND Patient must have achieved the 50th percentile growth velocity for bone age plus sex following the most recent supply; or Patient must have achieved an increase in height standard deviation score for chronological age plus sex following the most recent supply; or Patient must have achieved a minimum growth velocity of 4 cm per year following the most recent supply; or Patient must have achieved a mid-parental height standard deviation score following the most recent supply; or The treatment must have been administered at a dose that is lower than that recommended in the approved Product Information in the most recent supply; AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND Patient must not have an active tumour or evidence of tumour growth or activity; AND Patient must be male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND Patient must be male and must not have a height greater than or equal to 167.7cm; or	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 female and must not have a height greater than or equal to 155.0cm; AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include 1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months. 2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years. 3. The final adult height (in cm) of the patient's mother and father (where available). 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). Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction. Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C13309	P13309	CN13309	Somatrogon	Short stature and slow growth Change of drug Patient must be undergoing existing PBS-subsidised growth hormone treatment where the prescribed drug is changing within the same PBS indication - subsidy through this treatment phase must not: (i) initiate treatment, (ii) recommence treatment, (iii) reclassify the PBS indication; 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 have been treated with PBS-subsidised growth hormone for less than 32 weeks; or Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) having been demonstrated; or Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) not demonstrated due to at least one of: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance to treatment arising from social/family problems, (v) sub-optimal dosing (i.e. the dose was less than the permitted upper dose range); AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND Patient must not have an active tumour or evidence of tumour growth or activity; AND Patient must be male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND Patient must be male and must not have a height greater than or equal to 167.7cm; or Patient must be female and must not have a height greater than or equal to 155.0cm; AND Must be treated by a specialist or consultant physician in paediatric endocrinology; or Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology; AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. Definition An adequate response to the preceding supply of growth hormone for which the patient is changing from is one where the patient, for their sex, has achieved at least one of (a) the 50th percentile growth velocity for bone age; (b) an increase in height standard deviation score for chronological age; (c) a minimum growth velocity of 4 cm per year;	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(d) a mid-parental height standard deviation score. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include 1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months. 2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years. Where growth data has been supplied within 3 months of this authority application, do not resupply this data. 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). Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction. Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C13311	P13311	CN13311	Somatrogon	Short stature associated with biochemical growth hormone deficiency Continuing treatment Patient must be undergoing continuing PBS-subsidised therapy with this drug - subsidy through this treatment phase must not: (i) initiate treatment, (ii) change the prescribed drug, (iii) recommence treatment, (iv) reclassify the PBS indication; AND Patient must have achieved the 50th percentile growth velocity for bone age plus sex following the most recent supply; 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 have achieved an increase in height standard deviation score for chronological age plus sex following the most recent supply; or Patient must have achieved a minimum growth velocity of 4 cm per year following the most recent supply; or Patient must have achieved a mid-parental height standard deviation score following the most recent supply; or The treatment must have been administered at a dose that is lower than that recommended in the approved Product Information in the most recent supply; AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND Patient must not have an active tumour or evidence of tumour growth or activity; AND Patient must be male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include 1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months. 2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years. 3. The final adult height (in cm) of the patient's mother and father (where available). 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). Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction. Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C13312	P13312	CN13312	Somatrogon	Short stature and slow growth Continuing treatment as a reclassified patient Patient must be undergoing continuing PBS-subsidised therapy with this drug where the most recent authority approval for this drug was for a different PBS indication to that stated above - subsidy through this treatment phase must not: (i) initiate treatment, (ii) change the prescribed drug, (iii) recommence treatment, (iv) reclassify the PBS indication where the most recent authority approval was for a different growth hormone, (v) reclassify the PBS indication and recommence treatment simultaneously; AND The treatment must not be for the purposes of continuing treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose; AND Patient must have had a height no higher than the 1st percentile for age plus sex at the time treatment first commenced; AND Patient must have had a growth velocity below the 25th percentile for bone age plus sex measured over a 12 month interval (or a 6 month interval for an older child) prior to having commenced treatment; or Patient must have had an annual growth velocity of no higher than 8 cm per year where the patient had either a bone/chronological age no higher than 2.5 years prior to having commenced treatment; AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND Patient must not have an active tumour or evidence of tumour growth or activity; 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 male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND Patient must be male and must not have a height greater than or equal to 167.7cm; or Patient must be female and must not have a height greater than or equal to 155.0cm; AND Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include 1. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment where the patient had a chronological age greater than 2.5 years at commencement of treatment. 2. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months. 3. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years. 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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Advice). Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction. Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C13318	P13318	CN13318	Somatrogon	Short stature and slow growth Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must be undergoing privately funded treatment (e.g. through a clinical trial, a sponsor compassionate access program, supply from an overseas jurisdiction) with this drug at the time of this authority application - subsidy through this treatment phase must only occur once per lifetime; AND The treatment must not be for the purposes of continuing treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose; AND Patient must have had a height no higher than the 1st percentile for age plus sex at the time treatment first commenced; AND Patient must have had a growth velocity below the 25th percentile for bone age plus sex measured over a 12 month interval (or a 6 month interval for an older child) prior to having commenced treatment; or Patient must have had an annual growth velocity of no higher than 8 cm per year where the patient had either a bone/chronological age no higher than 2.5 years prior to having commenced treatment; AND Patient must not have a condition with a known risk of malignancy including	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)
				chromosomal abnormalities such as Down and Bloom syndromes; AND	
				Patient must not have an active tumour or evidence of tumour growth or activity; AND	
				Patient must be male and must not have a height greater than or equal to 167.7 cm; or	
				Patient must be female and must not have a height greater than or equal to 155.0 cm; AND	
				Patient must be male and must not have a bone age of 15.5 years or more; or	
				Patient must be female and must not have a bone age of 13.5 years or more; AND	
				Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or	
				Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND	
				Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.	
				Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include	
				1. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment where a patient had a chronological age greater than 2.5 years at commencement of treatment; OR	
				(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age plus sex immediately prior to commencing treatment.	
				2. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.	
				3. A bone age result performed within the last 12 months where the patient has chronological age greater than 2.5 years.	
				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). Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction. Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C13320	P13320	CN13320	Mecasermin	Severe growth failure with primary insulin-like growth factor-1 deficiency Initial treatment The condition must be caused by severe primary insulin-like growth factor-1 deficiency (IGFD), with IGFD deficiency for the purpose of PBS subsidy defined as a basal IGF-1 level (measured any time prior to initiating treatment with this drug) below the 2.5th percentile adjusted for each of: (i) age, (ii) gender; AND The condition must have resulted in the patient experiencing short stature, with short stature for the purpose of PBS subsidy defined as the patient's height (measured any time prior to initiating treatment with this drug) being at least 3 standard deviations below the norm, adjusted for each of: (i) age, (ii) gender; AND Patient must have a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); AND The condition must not be caused by growth hormone deficiency; AND Patient must have a bone age of less than 13.5 years (females); or Patient must have a bone age of less than 15.5 years (males); AND The condition must not be caused by secondary causes of IGFD - prior to initiating treatment with this drug, the treating physician has at least excluded each of the following: (i) malnutrition, (ii) hypopituitarism, (iii) hypothyroidism, (iv) medication side effects;	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)
				AND The treatment must not be in a patient with known epiphyseal closure/growth plate fusion (i.e. the patient is known to have ceased growing); AND Must be treated by a paediatric endocrinologist; the authority application must be completed by this physician type; or Must be treated by a paediatrician who has consulted the above mentioned specialist type; the authority application must be completed by this paediatrician; Patient must be aged from 2 years up until their 18th birthday. An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years. The initial treatment 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 the following (1) Insulin-like growth factor-1 deficiency (2) Short stature (3) Normal growth hormone levels (4) Bone age (where the patient has a chronological age of at least 2.5 years): (5) The patient's weight (kg); (6) The prescribed dose (mg/kg) (between 0.04 to 0.12); (7) The number of vials rounded to the nearest whole number, to provide sufficient drug quantity for 30 days of treatment per dispensing - see the relevant 'NOTE' attached to this listing for guidance. State each of (a) the patient's most recent basal IGF-1 level measured (ng/mL), (b) the measurement date (dd/mm/yy), (c) the name of the pathology result provider; (2) Short stature (3) Normal growth hormone levels (4) Bone age (where the patient has a chronological age of at least 2.5 years): (5) The patient's weight (kg); (6) The prescribed dose (mg/kg) (between 0.04 to 0.12); (7) The number of vials rounded to the nearest whole number, to provide sufficient drug quantity for 30 days of treatment per dispensing - see the relevant 'NOTE' attached to	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				this listing for guidance. State the patient's height (cm); (3) Normal growth hormone levels (4) Bone age (where the patient has a chronological age of at least 2.5 years): (5) The patient's weight (kg); (6) The prescribed dose (mg/kg) (between 0.04 to 0.12); (7) The number of vials rounded to the nearest whole number, to provide sufficient drug quantity for 30 days of treatment per dispensing - see the relevant 'NOTE' attached to this listing for guidance. State the patient's most recent growth hormone level measurement (mcg/L) - this figure must be greater than 6.6 mcg/L; (4) Bone age (where the patient has a chronological age of at least 2.5 years): (5) The patient's weight (kg); (6) The prescribed dose (mg/kg) (between 0.04 to 0.12); (7) The number of vials rounded to the nearest whole number, to provide sufficient drug quantity for 30 days of treatment per dispensing - see the relevant 'NOTE' attached to this listing for guidance. State each of (a) the patient's bone age in numerical figures at the time when it was most recently determined, (b) the date (dd/mm/yy) of this determination that is within 12 months of this authority application; (5) The patient's weight (kg); (6) The prescribed dose (mg/kg) (between 0.04 to 0.12); (7) The number of vials rounded to the nearest whole number, to provide sufficient drug quantity for 30 days of treatment per dispensing - see the relevant 'NOTE' attached to this listing for guidance. Height, growth velocity and weight measurements must not be more than three months old at the time of application. 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).	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13321	P13321	CN13321	Trientine	Chelation of elevated copper levels Patient must have a diagnosis of Wilson disease; AND Patient must be intolerant to penicillamine; AND Must be treated by a specialist medical practitioner, where this authority application is to initiate treatment with this drug, of the following type: (i) gastroenterologist, (ii) hepatologist, (iii) neurologist; the authority prescription must be completed by the specialist prescriber. or Must be treated by a medical practitioner (of any type), where this authority application is continuing established trientine treatment (of any specified salt) initiated by one of the above mentioned specialist types. or Must be treated by a nurse practitioner where this authority application is continuing established trientine treatment (of any specified salt) initiated by one of the above mentioned specialist types. Prior to seeking the initial authority approval, establish evidence of excess copper levels based on at least one of (i) clinical symptoms, (ii) measured serum copper levels, (iii) measured urinary copper levels. Document what these findings were in the patient's medical records. Do not supply them in this authority application. Refer to the following definitions if in doubt over what constitutes an acceptable intolerance to penicillamine Side effects of penicillamine occurring soon after initiation (within first few weeks/months) (i) fever, (ii) rash, (iii) enlarged lymph nodes, (iv) neutropenia, (v) thrombocytopenia, (vi) proteinuria, (vii) severe, persistent nausea. (i) nephrotic syndrome, (ii) glomerulonephritis, (iii) total bone marrow aplasia, (iv) skin changes (cutis laxa, elastosis perforans serpiginosa, pemphigus), (v) myasthenia gravis, (vi) polymyositis, (vii) Goodpasture syndrome, (viii) optic neuritis, (ix) proteinuria (1-2 grams/day or equivalent in children, depending on specialist Wilson disease and renal review), (x) haematuria (if cause unknown), (xi) thrombocytopenia/leukopenia, (xii) bleeding related to thromobocytopenia/leukopenia, (xiii) lupus-like syndrome (haematuria, proteinuria, positive antinuclear antibody), (xiv) arthralgia. Side effects of penicillamine developing later (i) nephrotic syndrome, (ii) glomerulonephritis, (iii) total bone marrow aplasia, (iv) skin	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				changes (cutis laxa, elastosis perforans serpiginosa, pemphigus), (v) myasthenia gravis, (vi) polymyositis, (vii) Goodpasture syndrome, (viii) optic neuritis, (ix) proteinuria (1-2 grams/day or equivalent in children, depending on specialist Wilson disease and renal review), (x) haematuria (if cause unknown), (xi) thrombocytopenia/leukopenia, (xii) bleeding related to thromobocytopenia/leukopenia, (xiii) lupus-like syndrome (haematuria, proteinuria, positive antinuclear antibody), (xiv) arthralgia. At the time of the first authority application for this drug, document the details (date of reaction, severity of reaction, dose of penicillamine, etc) of the penicillamine intolerance, if not already done, in the patient's medical records. Do not supply these details in this authority application.	
C13336	P13336	CN13336	Aflibercept Dexamethasone Faricimab Ranibizumab	Central retinal vein occlusion with macular oedema Continuing treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 13336
C13337	P13337	CN13337	Aflibercept Ranibizumab	Subfoveal choroidal neovascularisation (CNV) Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND The condition must be due to pathologic myopia (PM); AND The condition must be diagnosed by optical coherence tomography; or The condition must be diagnosed by fluorescein angiography; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. (a) A completed authority prescription form; 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)
				(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). If the application is submitted through HPOS form upload or mail, it must include (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.	
C13340	P13340	CN13340	Ranibizumab	Subfoveal choroidal neovascularisation (CNV) Continuing treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND The condition must not be due to pathologic myopia; AND The condition must not be due to age-related macular degeneration; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.	Compliance with Authority Required procedures - Streamlined Authority Code 13340
C13384	P13384	CN13384	Aflibercept Ranibizumab	Branch retinal vein occlusion with macular oedema Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO); AND Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment; AND The condition must be diagnosed by optical coherence tomography; or The condition must be diagnosed by fluorescein angiography; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. (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). If the application is submitted through HPOS form upload or mail, it must include (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.	
C13387	P13387	CN13387	Aflibercept Dexamethasone Faricimab Ranibizumab	Branch retinal vein occlusion with macular oedema Continuing treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 13387
C13390	P13390	CN13390	Aflibercept Ranibizumab	Central retinal vein occlusion with macular oedema Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO); AND Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen	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)
				equivalent 20/40 to 20/320), in the eye proposed for treatment; AND The condition must be diagnosed by optical coherence tomography; or The condition must be diagnosed by fluorescein angiography; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. (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). If the application is submitted through HPOS form upload or mail, it must include (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.	
C13392	P13392	CN13392	Aflibercept Ranibizumab	Subfoveal choroidal neovascularisation (CNV) Continuing treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND The condition must be due to pathologic myopia (PM); AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.	Compliance with Authority Required procedures - Streamlined Authority Code 13392
C13402	P13402	CN13402	Aflibercept Faricimab	Diabetic macular oedema (DMO) Continuing treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar 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)
				consultation with an ophthalmologist; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND The treatment must be as monotherapy; or The treatment must be in combination with laser photocoagulation; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Code 13402
C13406	P13406	CN13406	Aflibercept Faricimab Ranibizumab	Subfoveal choroidal neovascularisation (CNV) Continuing treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND The condition must be due to age-related macular degeneration (AMD); AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.	Compliance with Authority Required procedures - Streamlined Authority Code 13406
C13411	P13411	CN13411	Cemiplimab	Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) Continuing treatment Patient must have previously received PBS-subsidised therapy with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first: (i) disease progression despite treatment with this drug, (ii) 24 months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.	Compliance with Authority Required procedures
C13419	P13419	CN13419	Cemiplimab	Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) Initial treatment covering the first 3 treatment cycles The condition must be unsuitable for each of: (i) curative surgical resection, (ii) curative radiotherapy; AND Patient must have had a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13422	P13422	CN13422	Ranibizumab	Subfoveal choroidal neovascularisation (CNV) Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND The condition must be due to age-related macular degeneration (AMD); AND The condition must be diagnosed by optical coherence tomography; or The condition must be diagnosed by fluorescein angiography; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. (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). If the application is submitted through HPOS form upload or mail, it must include (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.	Compliance with Written Authority Required procedures
C13423	P13423	CN13423	Dexamethasone	Central retinal vein occlusion with macular oedema Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO); AND Patient must have documented visual impairment defined as a best corrected visual	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment; AND The condition must be diagnosed by optical coherence tomography; or The condition must be diagnosed by fluorescein angiography; AND Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; or Patient must have failed prior treatment with VEGF inhibitors; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. (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). If the application is submitted through HPOS form upload or mail, it must include (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.	
C13424	P13424	CN13424	Aflibercept	Subfoveal choroidal neovascularisation (CNV) Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND The condition must be due to age-related macular degeneration (AMD); AND The condition must be diagnosed by optical coherence tomography; 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)
				The condition must be diagnosed by fluorescein angiography; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. (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). If the application is submitted through HPOS form upload or mail, it must include (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.	
C13426	P13426	CN13426	Brolucizumab	Subfoveal choroidal neovascularisation (CNV) Continuing treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND The condition must be due to age-related macular degeneration (AMD); AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.	Compliance with Authority Required procedures
C13427	P13427	CN13427	Ranibizumab	Subfoveal choroidal neovascularisation (CNV) Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND The condition must not be due to pathologic myopia; 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)
				The condition must not be due to age-related macular degeneration; AND The condition must be diagnosed by optical coherence tomography; or The condition must be diagnosed by fluorescein angiography; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. (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). If the application is submitted through HPOS form upload or mail, it must include (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.	
C13428	P13428	CN13428	Dexamethasone	Diabetic macular oedema (DMO) Continuing treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND Patient must have had a cataract removed in the treated eye; or Patient must be scheduled for cataract surgery in the treated eye; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND The treatment must be as monotherapy; or The treatment must be in combination with laser photocoagulation; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 13428

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13429	P13429	CN13429	Dexamethasone	Branch retinal vein occlusion with macular oedema Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO); AND Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment; AND The condition must be diagnosed by optical coherence tomography; or The condition must be diagnosed by fluorescein angiography; AND Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; or Patient must have failed prior treatment with VEGF inhibitors; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. (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). If the application is submitted through HPOS form upload or mail, it must include (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13432	P13432	CN13432	Pembrolizumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment - 3 weekly treatment regimen Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under both initial and continuing treatment restrictions, whichever comes first.	Compliance with Authority Required procedures - Streamlined Authority Code 13432
C13434	P13434	CN13434	Tepotinib	Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have a WHO performance status of 2 or less; AND Patient must have evidence of MET exon 14 skipping alterations in tumour material.	Compliance with Authority Required procedures - Streamlined Authority Code 13434
C13437	P13437	CN13437	Pembrolizumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment - 6 weekly treatment regimen Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must not exceed a total of 18 cycles or up to 24 months of treatment under both initial and continuing treatment restrictions, whichever comes first.	Compliance with Authority Required procedures - Streamlined Authority Code 13437
C13441	P13441	CN13441	Tepotinib	Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 13441

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13442	P13442	CN13442	Atezolizumab	Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC) 1,200 mg administered once every 3 weeks Patient must be both: (i) initiating treatment, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy; or Patient must be continuing existing PBS-subsidised treatment with this drug; or Patient must be both: (i) transitioning from existing non-PBS to PBS subsidised supply of this drug, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated; Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug; AND The treatment must be for the purpose of adjuvant therapy following all of: (i) surgical resection, (ii) platinum-based chemotherapy; AND The condition must have/have had, at treatment commencement, an absence of each of the following gene abnormalities confirmed via tumour material sampling: (i) an activating epidermal growth factor receptor (EGFR) gene mutation, (ii) an anaplastic lymphoma kinase (ALK) gene rearrangement; AND The condition must have/have had, at treatment commencement, confirmation of programmed cell death ligand 1 (PD-L1) expression on at least 50% of tumour cells; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.	Compliance with Authority Required procedures - Streamlined Authority Code 13442
C13443	P13443	CN13443	Atezolizumab	Locally advanced or metastatic non-small cell lung cancer Initial treatment - 3 weekly treatment regimen Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND	Compliance with Authority Required procedures - Streamlined Authority Code 13443

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must have progressed on or after prior platinum based chemotherapy. or The condition must have progressed after treatment with tepotinib.	
C13445	P13445	CN13445	Nivolumab	Locally advanced or metastatic non-small cell lung cancer Initial treatment as second-line drug therapy Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must have progressed on or after prior platinum based chemotherapy. or The condition must have progressed after treatment with tepotinib. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.	Compliance with Authority Required procedures - Streamlined Authority Code 13445
C13446	P13446	CN13446	Atezolizumab	Locally advanced or metastatic non-small cell lung cancer Initial treatment - 4 weekly treatment regimen Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The condition must have progressed on or after prior platinum based chemotherapy. or The condition must have progressed after treatment with tepotinib.	Compliance with Authority Required procedures - Streamlined Authority Code 13446
C13451	P13451	CN13451	Atezolizumab	Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC) 1,680 mg administered once every 4 weeks, or 840 mg every 2 weeks Patient must be both: (i) initiating treatment, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-	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)
				L1) inhibitor therapy; or Patient must be continuing existing PBS-subsidised treatment with this drug; or Patient must be both: (i) transitioning from existing non-PBS to PBS subsidised supply of this drug, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated; Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug; AND The treatment must be for the purpose of adjuvant therapy following all of: (i) surgical resection, (ii) platinum-based chemotherapy; AND The condition must have/have had, at treatment commencement, an absence of each of the following gene abnormalities confirmed via tumour material sampling: (i) an activating epidermal growth factor receptor (EGFR) gene mutation, (ii) an anaplastic lymphoma kinase (ALK) gene rearrangement; AND The condition must have/have had, at treatment commencement, confirmation of programmed cell death ligand 1 (PD-L1) expression on at least 50% of tumour cells; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.	Code 13451
C13556	P13556	CN13556	Adalimumab	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:	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) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a dermatologist. The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
C13558	P13558	CN13558	Lorlatinib	Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)	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)
				Continuing treatment The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.	
C13561	P13561	CN13561	Vericiguat	Chronic heart failure Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated. or The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated. or The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated.	Compliance with Authority Required procedures - Streamlined Authority Code 13561
C13599	P13599	CN13599	Adalimumab	Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; 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 have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; or Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age. Active joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measurements must be no more than 4 weeks old at the time of this application. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C13602	P13602	CN13602	Adalimumab	Severe Crohn disease Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; Patient must be at least 18 years of age; Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; or Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; or Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy.	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 Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below. or Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below. The authority application must be made in writing and must include (1) two completed authority prescription forms; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following (a) patient must have evidence of intestinal inflammation; (b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient. (i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. Evidence of intestinal inflammation includes (i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces higher than normal lactoferrin or calprotectin level; or	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction. All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				failure.	
C13609	P13609	CN13609	Adalimumab	Severe Crohn disease Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; or Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; or Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND Patient must have evidence of intestinal inflammation; or Patient must be assessed clinically as being in a high faecal output state; or Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient; AND Patient must not receive more than 16 weeks of treatment under this restriction;	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)
				Patient must be at least 18 years of age. The authority application must be made in writing and must include (1) two completed authority prescription forms; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Evidence of intestinal inflammation includes (i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition	

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.	
C13612	P13612	CN13612	Adalimumab	Severe chronic plaque psoriasis Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a dermatologist. The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the	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)
				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.	
C13624	P13624	CN13624	Leuprorelin	Central precocious puberty Initial treatment Must be treated by a paediatric endocrinologist; or Must be treated by an endocrinologist specialising in paediatrics; Patient must be of an age that is prior to their 10th birthday if female; or Patient must be of an age that is prior to their 11th birthday if male; Patient must have had onset of signs/symptoms of central precocious puberty prior to their 8th birthday if female. or Patient must have had onset of signs/symptoms of central precocious puberty prior to their 9th birthday if male.	
C13625	P13625	CN13625	Natalizumab	Clinically definite relapsing-remitting multiple sclerosis Must be treated by a neurologist; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support); AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord. or Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient. The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug.	Compliance with Authority Required procedures - Streamlined Authority Code 13625

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.	
C13650	P13650	CN13650	Adalimumab	Severe psoriatic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; 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 to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or	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)
				(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C13681	P13681	CN13681	Adalimumab	Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND Patient must have failed, in the 24 months immediately prior to the date of the	Compliance with Written Authority Required procedures

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

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

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.	
C13694	P13694	CN13694	Adalimumab	Severe psoriatic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; 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 The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.	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)
				Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C13718	P13718	CN13718	Natalizumab	Clinically definite relapsing-remitting multiple sclerosis Must be treated by a neurologist; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority Code 13718

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be ambulatory (without assistance or support); AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord. or Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient. The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug. For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.	
C13726	P13726	CN13726	Pembrolizumab	Relapsed or Refractory Hodgkin lymphoma Initial treatment Patient must have undergone an autologous stem cell transplant (ASCT) for this condition and have experienced relapsed or refractory disease post ASCT; or Patient must not be suitable for ASCT for this condition and have experienced relapsed or refractory disease following at least 2 prior treatments for this condition; AND Patient must not have received prior treatment with a PD-1 (programmed cell death-1) inhibitor for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; 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 13726
C13727	P13727	CN13727	Pembrolizumab	Relapsed or refractory primary mediastinal B-cell lymphoma Initial treatment The condition must be diagnosed as primary mediastinal B-cell lymphoma through	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)
				histological investigation combined with at least one of: (i) positron emission tomography - computed tomography (PET-CT) scan, (ii) PET scan, (iii) CT scan; AND Patient must have been treated with rituximab-based chemotherapy for this condition; AND Patient must be experiencing relapsed/refractory disease; AND Patient must be autologous stem cell transplant (ASCT) ineligible following a single line of treatment; or Patient must have undergone an autologous stem cell transplant (ASCT); or Patient must have been treated with at least 2 chemotherapy treatment lines for this condition, one of which must include rituximab-based chemotherapy; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; 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.	Code 13727
C13728	P13728	CN13728	Pembrolizumab	Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer Initial treatment Patient must be untreated for this PBS indication (i.e untreated for each of: (i) unresectable disease, (ii) metastatic disease); AND Patient must not have received prior treatment for colorectal cancer with each of: (i) a programmed cell death-1 (PD-1) inhibitor, (ii) a programmed cell death ligand-1 (PD-L1) inhibitor; AND Patient must have a WHO performance status of 0 or 1; AND Patient must have deficient mismatch repair (dMMR) colorectal cancer, as determined by immunohistochemistry test; 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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13730	P13730	CN13730	Pembrolizumab	Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition; 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.	Compliance with Authority Required procedures
C13731	P13731	CN13731	Pembrolizumab	Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND 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.	Compliance with Authority Required procedures - Streamlined Authority Code 13731
C13732	P13732	CN13732	Pembrolizumab	Relapsed or refractory primary mediastinal B-cell lymphoma 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	Compliance with Authority Required procedures - Streamlined Authority Code 13732

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C13735	P13735	CN13735	Pembrolizumab	Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx Initial treatment The condition must be incurable by local therapies in the locally advanced setting; AND Patient must not have had systemic therapy for this condition in the recurrent or metastatic setting prior to initiating PBS-subsidised treatment with this drug for this condition; AND Patient must not have experienced disease recurrence within 6 months of completion of systemic therapy if previously treated in the locally advanced setting; AND Patient must have had a WHO performance status of 0 or 1; AND The treatment must be either: (i) the sole PBS-subsidised therapy where the condition expresses programmed cell death ligand 1 (PD-L1) with a combined positive score (CPS) greater than or equal to 20 in the tumour sample, (ii) in combination with platinum-based chemotherapy, unless contraindicated or not tolerated; 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 13735
C13736	P13736	CN13736	Pembrolizumab	Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority Code 13736

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C13739	P13739	CN13739	Pembrolizumab	Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer Initial treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND The condition must have progressed on or after prior platinum based chemotherapy; or The condition must have progressed on or within 12 months of completion of adjuvant platinum-containing chemotherapy following cystectomy for localised muscle-invasive urothelial cancer; or The condition must have progressed on or within 12 months of completion of neoadjuvant platinum-containing chemotherapy prior to cystectomy for localised muscle-invasive urothelial cancer; AND Patient must have a WHO performance status of 2 or less; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition; 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 13739
C13741	P13741	CN13741	Pembrolizumab	Relapsed or Refractory Hodgkin lymphoma 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 treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; or	Compliance with Authority Required procedures - Streamlined Authority Code 13741

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C13745	P13745	CN13745	Bortezomib	Newly diagnosed systemic light chain amyloidosis Administration on Days 1, 8, 15 and 22 of six treatment cycles (28 days per cycle) in total Patient must be undergoing concurrent treatment with PBS-subsidised daratumumab for this PBS indication.	
C13753	P13753	CN13753	Leflunomide	Severe active rheumatoid arthritis Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; or Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate; AND The treatment must be initiated by a physician.	
C13769	P13769	CN13769	Brolucizumab	Subfoveal choroidal neovascularisation (CNV) Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND The condition must be due to age-related macular degeneration (AMD); AND Patient must have persistent macular exudation, as determined clinically and/or by optical coherence tomography or fluorescein angiography, despite at least 6 months of PBS-subsidised treatment with: 1. Aflibercept and/or 2. Ranibizumab and/or 3. Faricimab; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				include (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. (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). If the application is submitted through HPOS form upload or mail, it must include (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.	
C13771	P13771	CN13771	Leflunomide	Severe active psoriatic arthritis Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; or Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate; AND The treatment must be initiated by a physician.	
C13774	P13774	CN13774	Daratumumab	Newly diagnosed systemic light chain amyloidosis Continuing treatment from week 25 onwards (administered once every four weeks) Patient must have previously received PBS-subsidised treatment with this drug for this condition; 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 continuing treatment that does not extend treatment duration beyond whichever comes first: (i) disease progression, (ii) 96 cumulative weeks from the first administered dose, once in a lifetime.	Compliance with Authority Required procedures
C13839	P13839	CN13839	Nivolumab	Unresectable Stage III or Stage IV malignant melanoma	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)
				Maintenance treatment Patient must have previously received of up to maximum 4 doses of PBS-subsidised combined therapy with nivolumab and ipilimumab as induction for this condition; AND The treatment must be as monotherapy for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this PBS indication. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	Streamlined Authority Code 13839
C13867	P13867	CN13867	Ruxolitinib	Moderate to severe chronic graft versus host disease (cGVHD) Continuing treatment Patient must have received initial PBS-subsidised treatment with this drug for this condition; AND Patient must have responding disease at 24 weeks compared with baseline, demonstrated by either a: (i) partial response, (ii) complete response; AND The treatment must be the sole PBS-subsidised treatment for this condition with the exception of: (i) corticosteroids, (ii) calcineurin inhibitors; AND Must be treated by a haematologist. or Must be treated by an oncologist with allogeneic bone marrow transplantation experience. or Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types. Response is defined as attaining a complete or partial response as defined by the *National Institutes of Health* (NIH) criteria (Lee et al., 2015). Note that response is relative to the assessment of organ function affected by cGVHD prior to commencing initial treatment with ruxolitinib. (a) complete response is defined as complete resolution of all signs and symptoms of cGVHD in all evaluable organs without initiation or addition of new systemic therapy. (b) partial response is defined as an improvement in at least one organ (e.g. improvement of 1 or more points on a 4-to-7-point scale, or an improvement of 2 or	Compliance with Authority Required procedures - Streamlined Authority Code 13867

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				more points on a 10-to-12-point scale) without progression in other organs or sites, initiation or addition of new systemic therapies. The assessment of response must be documented in the patient's medical records. Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.	
C13868	P13868	CN13868	Sapropterin	Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU) Initial treatment - responsiveness testing The treatment must be for the purpose of ascertaining the patient's response to treatment over a period of 7 days, with the intent to then use the drug to control phenylalanine levels under the treatment phase: First continuing treatment, Indication: Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU); AND Patient must have a baseline blood phenylalanine level above 250 micromol/L prior to commencing treatment with this drug despite best efforts to rely on dietary modifications to control phenylalanine levels; AND Must be treated by a metabolic physician; AND Patient must be undergoing treatment with this drug for the first time; AND Patient must not be undergoing treatment with this drug under this Treatment phase, more than once per lifetime following completion of this authority application; AND Patient must not be undergoing simultaneous treatment with this drug under another PBS-listing (apply under either listing type, but not both simultaneously); Patient must be one of: (i) planning conception, (ii) pregnant.	Compliance with Authority Required procedures
C13876	P13876	CN13876	Ruxolitinib	Grade II to IV acute graft versus host disease (aGVHD) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a:	Compliance with Authority Required procedures - Streamlined Authority Code 13876

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(i) partial response (ii) complete response; AND Must be treated by a haematologist. or Must be treated by an oncologist with allogeneic bone marrow transplantation experience. or Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types. Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib. (a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD. (b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD. The assessment of response must be documented in the patient's medical records. Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.	
C13880	P13880	CN13880	Sapropterin	Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU) First continuing treatment Must be treated by a metabolic physician; or Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician; AND Patient must have previously received PBS-subsidised treatment under the Initial treatment - responsiveness testing restriction with this drug for this condition; AND Patient must have demonstrated a response to treatment with this drug of greater than or equal to a 30% reduction in phenylalanine levels from baseline during initial	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				responsiveness testing. Blood phenylalanine levels must be based on measurements taken during stable periods of the condition. Dietary phenylalanine intake must be maintained at a constant level.	
C13885	P13885	CN13885	Sapropterin	Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU) Initial treatment - responsiveness testing Must be treated by a metabolic physician; AND Patient must be untreated with this drug; or Patient must have completed prior responsiveness testing on only 1 occasion - this occurred when the patient was less than 1 month of age, but this benefit is for a second attempt at responsiveness testing in a patient aged at least 1 month old; AND Patient must have a baseline blood phenylalanine level above 360 micromole per L and be less than one month of age; or Patient must have a baseline blood phenylalanine level above 600 micromole per L and be more than one month of age; AND The treatment must be for the purpose of initial responsiveness testing for a period of 24 hours in a patient less than one month of age. or The treatment must be for the purpose of initial responsiveness testing for a period of 7 days in a patient aged more than one month. Dietary phenylalanine intake must be maintained at a constant level. Patients or their parent/guardian should be assessed for their ability to comply with the sapropterin protocol and PKU diet prior to conducting initial responsiveness testing.	Compliance with Authority Required procedures
C13892	P13892	CN13892	Ruxolitinib	Grade II to IV acute graft versus host disease (aGVHD) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a: (i) partial response (ii) complete response; AND Must be treated by a haematologist. or Must be treated by an oncologist with allogeneic bone marrow transplantation	Compliance with Authority Required procedures - Streamlined Authority Code 13892

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				experience. or Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types. Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib. (a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD. (b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD. The assessment of response must be documented in the patient's medical records. Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.	
C13900	P13900	CN13900	Nivolumab	Adjuvant treatment of stage II or III oesophageal cancer or gastro-oesophageal junction cancer The condition must have histological evidence confirming a diagnosis of a least one of: (i) adenocarcinoma, (ii) squamous cell cancer; document this evidence in the patient's medical records; AND The condition must have been treated with neoadjuvant platinum-based chemoradiotherapy; AND The treatment must be for the purposes of adjuvant use following complete surgical resection that occurred within 16 weeks prior to initiating this drug; AND The condition must have evidence, through resected specimen, that residual disease meets the Tumour Nodes Metastases (TNM) staging system (as published by the Union for International Cancer Control) of either:	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(i) at least ypT1, (ii) at least ypN1; document this evidence in the patient's medical records; AND Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must be undergoing treatment with a dosing regimen as set out in the drug's approved Australian Product Information; AND Patient must not be undergoing PBS-subsidised treatment with this drug where this prescription extends treatment beyond whichever comes first: (i) 12 months from treatment initiation, irrespective of whether initial treatment was PBS-subsidised/non-PBS-subsidised, (ii) disease recurrence despite treatment with this drug; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.	
C13906	P13906	CN13906	Ruxolitinib	Moderate to severe chronic graft versus host disease (cGVHD) Initial treatment Patient must have received prior systemic steroid treatment for this condition; AND Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment; AND The treatment must be the sole PBS-subsidised treatment for this condition with the exception of: (i) corticosteroids, (ii) calcineurin inhibitors; AND Must be treated by a haematologist; or Must be treated by an oncologist with allogeneic bone marrow transplantation experience; or Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation. The severity of cGVHD is defined by the *National Institutes of Health* (NIH) criteria (Jagasia et al., 2015) (a) Moderate cGVHD at least one organ (not lung) with a score of 2, 3 or more organs involved with a score of 1 in each organ, or lung score of 1	Compliance with Authority Required procedures - Streamlined Authority Code 13906

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(b) Severe cGVHD at least 1 organ with a score of 3, or lung score of 2 or 3 Steroid-refractory disease is defined as (a) a lack of response or disease progression after administration of a minimum prednisone dose of 1 mg/kg/day for at least 1 week (or equivalent); or (b) disease persistence without improvement despite continued treatment with prednisone at greater than 0.5 mg/kg/day or 1 mg/kg/every other day for at least 4 weeks (or equivalent). Steroid-dependent disease is defined as an increased prednisone dose to greater than 0.25 mg/kg/day after two unsuccessful attempts to taper the dose (or equivalent). Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal. Details of prior steroid use should be documented in the patient's medical records. A patient must demonstrate a response 24 weeks after initiating treatment with ruxolitinib to be eligible for continuing treatment. Response is defined as attaining a complete or partial response as defined by the *National Institutes of Health* (NIH) criteria (Lee et al., 2015). Note that response is relative to the assessment of organ function affected by cGVHD prior to commencing initial treatment with ruxolitinib. (a) complete response is defined as complete resolution of all signs and symptoms of cGVHD in all evaluable organs without initiation or addition of new systemic therapy. (b) partial response is defined as an improvement in at least one organ (e.g. improvement of 1 or more points on a 4-to-7-point scale, or an improvement of 2 or more points on a 10-to-12-point scale) without progression in other organs or sites, initiation or addition of new systemic therapies. The assessment of response must be documented in the patient's medical records. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.	
C13907	P13907	CN13907	Ruxolitinib	Grade II to IV acute graft versus host disease (aGVHD) Initial treatment Patient must have received prior systemic steroid treatment for this condition; AND Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to	Compliance with Authority Required procedures - Streamlined Authority Code 13907

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				steroid treatment; AND Must be treated by a haematologist. or Must be treated by an oncologist with allogeneic bone marrow transplantation experience. or Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types. The severity of aGVHD is defined by the Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Steroid-refractory disease is defined as (a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or (b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD. (a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or (b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days. Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria (a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or (b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days. Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal. Details of prior steroid use should be documented in the patient's medical records. A patient must demonstrate a response 14 days after initiating treatment with ruxolitinib to be eligible for continuing treatment. Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib. (a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD. (b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD. The assessment of response must be documented in the patient's medical records. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.	
C13911	P13911	CN13911	Ruxolitinib	Grade II to IV acute graft versus host disease (aGVHD) Initial treatment Patient must have received prior systemic steroid treatment for this condition; AND Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment; AND Must be treated by a haematologist. or Must be treated by an oncologist with allogeneic bone marrow transplantation experience. or Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types. The severity of aGVHD is defined by the Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Steroid-refractory disease is defined as (a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or (b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-	Compliance with Authority Required procedures - Streamlined Authority Code 13911

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				IV aGVHD. (a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or (b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days. Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria (a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or (b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days. Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal. Details of prior steroid use should be documented in the patient's medical records. A patient must demonstrate a response 14 days after initiating treatment with ruxolitinib to be eligible for continuing treatment. Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib. (a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD. (b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD. The assessment of response must be documented in the patient's medical records. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.	
C13912	P13912	CN13912	Sapropterin	Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU) Subsequent continuing	Compliance with Authority

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 metabolic physician; or Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must be undergoing regular phenylalanine testing and assessment of adherence to dietary modifications.	Required procedures
C13920	P13920	CN13920	Abacavir	Human immunodeficiency virus (HIV) infection Patient must be less than 13.00 years of age; Patient must be unable to take a solid dose form of this drug; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures
C13921	P13921	CN13921	Lenvatinib	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 and pembrolizumab 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.	Compliance with Authority Required procedures - Streamlined Authority Code 13921
C13923	P13923	CN13923	Asciminib	Chronic Myeloid Leukaemia (CML) Continuing treatment for patients without T315I mutation The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have received initial PBS-subsidised treatment with this drug for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority Code 13923

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C13925	P13925	CN13925	Asciminib	Chronic Myeloid Leukaemia (CML) Initial PBS-subsidised treatment for patients with T315I mutation The condition must not be in the blast phase; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must be expressing the T315I mutation confirmed through a bone marrow biopsy pathology report; AND The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; or The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND Patient must have failed an adequate trial of at least one tyrosine kinase inhibitor as confirmed through a pathology report from an Approved Pathology Authority. or Patient must have experienced intolerance, not failure to respond, to at least one tyrosine kinase inhibitor as confirmed through a pathology report from an Approved Pathology Authority. Failure of an adequate trial of a tyrosine kinase inhibitor is defined as 1. Lack of response defined as either (i) failure to achieve a haematological response after a minimum of 3 months therapy; or (ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive (Ph+) cells; or (iii) failure to achieve or maintain a major cytogenetic response or a peripheral blood	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)
				BCR-ABL level of less than 1% after a minimum of 12 months therapy; OR 2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph+ cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR 3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR 4. Development of accelerated phase in a patient previously prescribed a TKI inhibitor for any phase of chronic myeloid leukaemia; OR 5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during TKI therapy in patients with accelerated phase chronic myeloid leukaemia. Accelerated phase is defined by the presence of 1 or more of the following 1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or 2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or 3. Peripheral basophils greater than or equal to 20%; or 4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or 5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome). The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include (i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or (ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and (iii) details (date, unique identifying number/code or provider number) of a bone marrow	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				biopsy pathology report demonstrating evidence of the T315I mutation; and (iv) where there has been a loss of response to imatinib or dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib, ponatinib or asciminib at any one time and must not be receiving concomitant interferon alfa therapy Up to a maximum of 18 months of treatment may be authorised under this initial restriction.	
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	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)
				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.	
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	Mild to moderately severe Alzheimer disease Initial	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Galantamine Rivastigmine	Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs. Patients who qualify under this criterion are from 1 or more of the following groups (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background; (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate; (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test; (4) Intellectual (developmental or acquired) disability, eg Down's syndrome; (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test; (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment. Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.	
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. 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	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)
				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
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	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)
				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.	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 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	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)
				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 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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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).	
C13958	P13958	CN13958	Upadacitinib	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 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.	Compliance with Authority Required procedures
C13959	P13959	CN13959	Upadacitinib	Moderate to severe ulcerative colitis Dose modification	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)
				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.	
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. 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 13966
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)	Compliance with Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must 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.	Required procedures - Streamlined Authority Code 13972
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	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)
				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.	
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	Compliance with Written Authority Required procedures

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), 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. 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	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)
				has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.	
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 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	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) 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 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:	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)
				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. 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	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 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. 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	

Clause 1

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. 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	Compliance with Authority Required procedures - Streamlined Authority Code 14001

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

Clause 1

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 break in biological medicine of less than 5 years) or Initial 3 (recommencement 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)
				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.	
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. 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	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)
				(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. 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	Compliance with Authority Required procedures

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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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).	
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 gastroenterology (code 81)]. or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].	Compliance with Authority Required procedures - Streamlined Authority Code 14017
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:	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)
				(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. 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	

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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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 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	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)
				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 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).	Compliance with Authority Required procedures
C14027	P14027	CN14027	Pembrolizumab	Advanced, metastatic or recurrent endometrial carcinoma	Compliance with Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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; 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.	Required procedures - Streamlined Authority Code 14027
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	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)
				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.	
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).	Compliance with Authority Required procedures

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

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

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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

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 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

Clause 1

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.	
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 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	Compliance with Authority Required procedures

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

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.	
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	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)
				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 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	

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.	
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

Clause 1

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.	
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 least 4 active major joints; 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 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 within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 medical records. The following criteria indicate failure to achieve an adequate response to prior therapy	Compliance with Authority Required procedures

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

Clause 1

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

Clause 1

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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Initial treatment - Initial 1 (new patient weighing less than 30 kg)	Required procedures
				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 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	

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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 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	Compliance with Authority Required procedures - Streamlined Authority Code 14097

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

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 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% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application. The assessment of the patient's response to the most recent course of biological	Compliance with Authority Required procedures - Streamlined Authority Code 14104

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
C14107	P14107	CN14107	Adalimumab	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 14107

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. 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.	
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	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)
				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 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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 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	Compliance with Authority Required procedures - Streamlined Authority Code 14136

Clause 1

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

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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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 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	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)
				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.	
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	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)
				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. 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	Compliance with Authority Required procedures - Streamlined Authority Code 14154

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 per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application. At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 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	Compliance with Authority Required procedures - Streamlined Authority Code 14155

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
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	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). The assessment of response to treatment must be documented in the patient's medical records. 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)	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 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 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.	

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 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

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. The following reports must be documented in the patient's medical records where	

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

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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 Upadacitinib	Non-radiographic axial spondyloarthritis 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	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 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.	
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
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
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	

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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; 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 Amlodipine with atorvastatin Atenolol Atorvastatin Baclofen Beclometasone Bimatoprost Brimonidine Brinzolamide	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Budesonide		
			Candesartan		
			Chlortalidone		
			Ciclesonide		
			Ciclosporin		
			Clonidine		
			Clopidogrel		
			Clopidogrel with aspirin		
			Colestyramine		
			Cyproterone		
			Dexamethasone		
			Diltiazem		
			Dorzolamide		
			Enalapril		
			Eprosartan		
			Estradiol		
			Estradiol and estradiol with dydrogesterone		
			Estradiol and estradiol with norethisterone		
			Estradiol with		

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			norethisterone		
			Estriol		
			Everolimus		
			Ezetimibe		
			Ezetimibe and rosuvastatin		
			Ezetimibe with atorvastatin		
			Ezetimibe with simvastatin		
			Famotidine		
			Felodipine		
			Fenofibrate		
			Fluticasone furoate		
			Fluticasone propionate		
			Fluvastatin		
			Furosemide		
			Gemfibrozil		
			Glibenclamide		
			Gliclazide		
			Glimepiride		
			Glipizide		

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Glyceryl trinitrate		
			Hydrochlorothiazide		
			Hydrochlorothiazide with amiloride		
			Indapamide		
			Irbesartan		
			Isosorbide dinitrate		
			Isosorbide mononitrate		
			Labetalol		
			Latanoprost		
			Lercanidipine		
			Lisinopril		
			Medroxyprogesterone		
			Metformin		
			Methenamine		
			Methotrexate		
			Metoprolol		
			Mycophenolic acid		
			Nicorandil		
			Nifedipine		
			Nizatidine		
			Norethisterone		

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Olmesartan		
			Paraffin		
			Perindopril		
			Perindopril with indapamide		
			Pilocarpine		
			Pizotifen		
			Potassium chloride		
			Potassium chloride with potassium bicarbonate		
			Pravastatin		
			Prazosin		
			Prednisolone		
			Prednisone		
			Probenecid		
			Progesterone		
			Progesterone and estradiol		
			Propranolol		
			Pyridostigmine		
			Ramipril		
			Rosuvastatin		

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Simvastatin		
			Sirolimus		
			Sodium bicarbonate		
			Spironolactone		
			Tacrolimus		
			Telmisartan		
			Timolol		
			Toremifene		
			Trandolapril		
			Tranylcypromine		
			Travoprost		
			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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 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	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 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: (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.	Code 14254
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	Hypertension The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			amlodipine Telmisartan with amlodipine	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.	
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
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 Code 14264

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.	
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 quantity	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)
				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.	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.	
C14291	P14291	CN14291	Alendronic acid	Established osteoporosis	

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 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 Patient must have a history of venous thromboembolism.	Compliance with Authority Required procedures - Streamlined Authority Code 14300
C14301	P14301	CN14301	Apixaban	Prevention of stroke or systemic embolism The condition must be stable for the prescriber to consider the listed maximum quantity	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)
			Dabigatran etexilate Rivaroxaban	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.	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.	
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-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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be due to renal disease.	Compliance with Authority Required procedures - Streamlined Authority Code 14322
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.	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)
				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.	
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 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.	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)
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 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.	Compliance with Authority Required procedures - Streamlined Authority 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	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)
				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.	
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 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.	Compliance with Authority Required procedures
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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 The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses).	Compliance with Authority Required procedures
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	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)
				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.	
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).	Compliance with Authority Required procedures - Streamlined Authority Code 14363

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

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

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
C14375	P14375	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	Compliance with Written Authority Required procedures

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

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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.	
C14377	P14377	CN14377	Adalimumab	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 treatment - Initial 1, Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following	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)
				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 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

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 at least 18 years of age; Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	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 unable to swallow. or Patient must be contraindicated to oral anti-emetics.	
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% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Provide details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of the most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response once only through the Authority application for lenalidomide.	Compliance with Authority Required procedures - Streamlined Authority Code 14389
C14396	P14396	CN14396	Bimekizumab	Severe chronic plaque psoriasis Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment	Compliance with Written Authority Required

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to 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	procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	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 receive more than 16 weeks of treatment under this restriction; Patient must be aged 18 years or older; Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where	

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

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]. 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.	
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;	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 be aged 18 years or older; Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application. The 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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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. 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 -	Compliance with Authority Required procedures - Streamlined Authority Code 14403

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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-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.	Compliance with Authority Required procedures - Streamlined Authority Code 14404
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 following being true: (i) all other PBS eligibility criteria in this restriction are met, (ii) disease progression is	Compliance with Authority Required procedures - Streamlined Authority Code 14416

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

Clause 1

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]. 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.	
C14428	P14428	CN14428	Guselkumab	Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body (new patient)	Compliance with Written Authority Required

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

Clause 1

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

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) 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.	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The authority application must be made in writing and must include (a) a completed authority prescription form(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.	
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;	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. An adequate response to treatment is defined as A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to 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	

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				restriction.	
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 (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates 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)
				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 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	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)
				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; 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	Compliance with Written Authority Required procedures

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

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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be aged 18 years or older; Must be treated by a dermatologist.	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include (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	

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

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				assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of 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.	
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.	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 treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include (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	

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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. 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	Compliance with Authority Required procedures - Streamlined Authority Code 14471

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				cause; AND Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.	
C14483	P14483	CN14483	Adalimumab Baricitinib Tocilizumab Tofacitinib Upadacitinib	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 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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient fails to demonstrate a response to treatment with this drug under this	

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. 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 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

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.	
C14488	P14488	CN14488	Abatacept Adalimumab	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	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)
			Baricitinib Etanercept Golimumab Tocilizumab Tofacitinib Upadacitinib	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.	
C14493	P14493	CN14493	Adalimumab Baricitinib Certolizumab pegol 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 or either marker reduced by at least 20% from baseline; AND either of the following (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
C14496	P14496	CN14496	Adalimumab	Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient)	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)
				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: (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	

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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records (a) the active joint count, ESR and/or CRP result and date of results; (b) details of prior treatment, including dose and date/duration of treatment. (c) If applicable, details of any contraindications/intolerances. (d) If applicable, the maximum tolerated dose of methotrexate. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
C14498	P14498	CN14498	Adalimumab Baricitinib 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	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 with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; or Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs,	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				however the time on treatment must be at least 6 months. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				phase (the latest version is located on the website specified in the Administrative Advice). An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug 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 Etanercept Tocilizumab Tofacitinib Upadacitinib	Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; 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	Compliance with Authority Required procedures - Streamlined Authority Code 14499

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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 restriction. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The assessment of response to treatment must be documented in the patient's medical records. The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.	Compliance with Authority Required procedures - Streamlined Authority Code 14508
C14509	P14509	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	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 treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose; AND Patient must have demonstrated an adequate response to treatment; AND Patient must not receive more than 8 weeks of treatment with etanercept under this restriction. An adequate response to treatment is defined as A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The assessment of response to treatment must be documented in the patient's medical records. The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.	
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	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 not receive more than 16 weeks of treatment with this biological medicine under this restriction; Patient must be under 18 years of age. Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be documented in the patient's medical records. Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be documented in the patient's medical records. Details of the accepted toxicities including severity can be found on the Services Australia website. The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy (a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy. (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.	

Clause 1

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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
C14522	P14522	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:	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)
				(i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; or Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; Patient must be at least 18 years of age. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs,	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				however the time on treatment must be at least 6 months. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. The authority application must be made in writing and must include	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Initial treatment with an I.V. loading dose Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats. Initial treatment with no loading dose One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
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	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 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.	
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 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.	Compliance with Authority Required procedures
C14554	P14554	CN14554	Etanercept	Severe chronic plaque psoriasis Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient	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)
				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. 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	

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

Clause 1

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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	

Clause 1

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. 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 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	Compliance with Written Authority Required procedures

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 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.	

Clause 1

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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Initial treatment with an I.V. loading dose Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats. Initial treatment with no loading dose One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this	

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.	
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 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.	Compliance with Authority Required procedures - Streamlined Authority Code 14563
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	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)
				(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	