

National Health (Listing of Pharmaceutical Benefits) Instrument 2024

PB 26 of 2024

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

National Health Act 1953

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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–K)

Volume 3: Schedule 1 (Part 1: L–P)

Volume 4: Schedule 1 (Part 1: Q–Z, Part 2), Schedules 2 and 3

Volume 5: Schedule 4 (Part 1: C4076–C9993)

Volume 6: Schedule 4 (Part 1: C10020–C12999)

**Volume 7: Schedule 4 (Part 1: C13006–C13925)**

Volume 8: Schedule 4 (Part 1: C13927–C14567)

Volume 9: Schedule 4 (Part 1: C14568–C16252, Part 2)

Volume 10: Schedules 5, 6 and Endnotes

Each volume has its own contents

**About this compilation**

**This compilation**

This is a compilation of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* that shows the text of the law as amended and in force on 1 January 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. Any uncommenced amendments affecting the law are accessible on the Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the Register for the compiled law.

**Application, saving and transitional provisions for provisions and amendments**

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

**Editorial changes**

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

**Modifications**

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

**Self-repealing provisions**

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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Schedule 4—Circumstances, purposes, conditions and variations

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

Part 1—Circumstances, purposes and conditions

1 Circumstances, purposes and conditions

The following table sets out:

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

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

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

| **Circumstances Code** | **Purposes Code** | **Conditions Code** | **Listed Drug** | **Circumstances and Purposes** | **Authority Requirements (part of Circumstances; or Conditions)** |
| --- | --- | --- | --- | --- | --- |
| 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  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  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  (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). | Compliance with Written Authority Required procedures |
| 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  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. | Compliance with Authority Required procedures |
| 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 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). | Compliance with Written Authority Required procedures |
| 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 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 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. | Compliance with Written Authority Required procedures |
| 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 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 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. | Compliance with Written Authority Required procedures |
| C13034 | P13034 | CN13034 | Diroximel fumarate | Multiple sclerosis  Continuing treatment  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND  The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not show continuing progression of disability while on treatment with this drug.  Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 13034 |
| 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 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 |
| 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 |
| C13043 | P13043 | CN13043 | Infliximab | Severe psoriatic arthritis  Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  The treatment must have both:   (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be at least 18 years of age.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. | 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 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 |
| 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 |
| C13056 | P13056 | CN13056 | Infliximab | Complex refractory Fistulising Crohn disease  Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form  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  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.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An adequate response is defined as  (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or  (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.  The most recent fistula assessment must be no more than 1 month old at the time of application. | Compliance with Authority Required procedures |
| 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 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 |
| C13061 | P13061 | CN13061 | Infliximab | Moderate to severe ulcerative colitis  Balance of supply for Initial treatment, Continuing treatment - 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 for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks 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 treatment available under the Continuing treatment - subcutaneous form;  Patient must be at least 18 years of age. | Compliance with Authority Required procedures |
| C13068 | P13068 | CN13068 | Infliximab | Severe Crohn disease  Balance of supply for Initial treatment, Continuing treatment - 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 for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks 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 treatment available under the Continuing treatment - subcutaneous form;  Patient must be at least 18 years of age. | Compliance with Authority Required procedures |
| 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;  (ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application. | Compliance with Authority Required procedures |
| C13072 | P13072 | CN13072 | Diroximel fumarate | Multiple sclerosis  Initial treatment  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND  The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND  Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND  Patient must be ambulatory (without assistance or support).  Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 13072 |
| 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 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 |
| C13079 | P13079 | CN13079 | Infliximab | Severe chronic plaque psoriasis  Continuing treatment (whole body, or, face/hand/foot) with subcutaneous form or switching from intravenous form to subcutaneous form  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  The treatment must have both:   (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy; 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 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).  Where the condition is affecting the whole body, an adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by at least 75%, or, is sustained at this level, when compared with the baseline value for this treatment cycle. State the qualifying PASI score in the authority application.  Where the condition is affecting the face/hand/foot, 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. Indicate the rating (0=none, 1=slight) for each of these 3 observations in the authority application for each affected area; or  (ii) A reduction by at least 75% in the skin area affected, or, sustained at this level, as compared to the baseline value for this treatment cycle. State the qualifying numerical percentage figure in the authority application for each affected area.  All assessment findings must be no more than 1 month old at the time of application. Response assessments must be performed on the same affected area assessed at baseline. | Compliance with Authority Required procedures |
| 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 approving this authority application. | Compliance with Authority Required procedures |
| 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 |
| 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 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 |
| C13104 | P13104 | CN13104 | Infliximab | Severe active rheumatoid arthritis  Balance of supply for Initial treatment, Continuing treatment - subcutaneous form  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have received insufficient therapy with this drug for this condition under the Initial treatment with subcutaneous form restriction to complete 22 weeks initial treatment (intravenous and subcutaneous inclusive); or  Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment; AND  The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; AND  The treatment must provide no more than the balance of up to 22 weeks treatment available under the Initial treatment - subcutaneous form; or  The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form;  Patient must be at least 18 years of age. | Compliance with Authority Required procedures |
| 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 |
| C13127 | P13127 | CN13127 | Ruxolitinib | High risk and intermediate-2 risk myelofibrosis  Initial treatment  The condition must be either:   (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report.  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 bone marrow biopsy report confirming diagnosis of myelofibrosis; and  (b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.  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 |
| C13128 | P13128 | CN13128 | Ruxolitinib | High risk and intermediate-2 risk myelofibrosis  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| C13130 | P13130 | CN13130 | Ruxolitinib | Intermediate-1 risk myelofibrosis  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| 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 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.) | Compliance with Authority Required procedures - Streamlined Authority Code 13132 |
| 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 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. | Compliance with Written Authority Required procedures |
| 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)  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 13168 |
| C13173 | P13173 | CN13173 | Ruxolitinib | Intermediate-1 risk myelofibrosis  Initial treatment  The condition must be either:   (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report; AND  Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy.  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 bone marrow biopsy report confirming diagnosis of myelofibrosis; and  b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS; and  c) A confirmation that the patient's disease related symptoms are resistant, refractory or intolerant to available therapy.  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 |
| 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 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. | Compliance with Written Authority Required procedures |
| 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  (a) a completed authority prescription form; and  (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | Compliance with Written Authority Required procedures |
| 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 phase (the latest version is located on the website specified in the Administrative Advice). | Compliance with Written Authority Required procedures |
| 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; and  (d) a declaration of whether the patient's disease is relapsed or refractory, and the date and means by which the patient's disease was assessed as being relapsed or refractory.  All reports must be documented in the patient's medical records.  If the application is submitted through HPOS form upload or mail, it must include  (i) A completed authority prescription form; and  (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | Compliance with Authority Required procedures |
| 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 examination report from an Approved Pathology Authority  All reports must be documented in the patient's medical records.  If the application is submitted through HPOS form upload or mail, it must include  (i) A completed authority prescription form; and  (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  The following reports must be documented in the patient's medical records  (a) bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia; and  (b) full blood examination report | Compliance with Authority Required procedures |
| 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 |
| C13208 | P13208 | CN13208 | Brentuximab vedotin | Relapsed or Refractory Hodgkin lymphoma  Continuing treatment  Patient must have undergone a primary autologous stem cell transplant (ASCT) for this condition; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND  Patient must not receive more than 12 cycles of treatment under this restriction.  The treatment must not exceed a total of 16 cycles of combined initial and continuing treatment in a lifetime. | Compliance with Authority Required procedures |
| C13209 | P13209 | CN13209 | Brentuximab vedotin | Relapsed or Refractory Hodgkin lymphoma  Initial treatment  Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition; AND  Patient must not be suitable for ASCT for this condition; or  Patient must not be suitable for treatment with multi-agent chemotherapy for this condition; AND  Patient must have experienced a relapsed CD30+ Hodgkin lymphoma following at least two prior treatments for this condition; or  Patient must have experienced a refractory CD30+ Hodgkin lymphoma following at least two prior treatments for this condition; AND  Patient must not receive more than 4 cycles of treatment under this restriction.  Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.  If the application is submitted through HPOS upload or mail, it must include  (a) a completed authority prescription form; and  (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | Compliance with Authority Required procedures |
| 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  The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.  Partial response is defined using Lugano Response Criteria for Non-Hodgkin Lymphoma as  (a) Positron emission tomography-based response lymph nodes and extralymphatic sites - a score of 4 (uptake moderately > liver), or 5 (uptake markedly higher than liver and/or new lesions), with reduced uptake compared with baseline and residual mass(es) of any size; nonmeasured lesions - not applicable; organ enlargement - not applicable; new lesions - none; bone marrow - residual uptake higher than uptake in normal marrow but reduced compared with baseline (diffuse uptake compatible with reactive changes from chemotherapy allowed). If there are persistent focal changes in the marrow in the context of a nodal response, consideration should be given to further evaluation with MRI or biopsy or an interval scan; OR  (b) Computed tomography-based response lymph nodes and extralymphatic sites - greater than or equal to 50% decrease in the sum of the product of the perpendicular diameters for multiple lesions, of up to six (6) target measurable nodes and extranodal sites; non-measured lesions - absent/normal, regressed but no increase; new lesions - none; bone marrow - not applicable. | Compliance with Authority Required procedures |
| C13230 | P13230 | CN13230 | Dapagliflozin  Empagliflozin | 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 m2 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.  Patients with polycystic kidney disease, lupus nephritis or ANCA-associated vasculitis; patients requiring or with a recent history of cytotoxic or immunosuppressive therapy for kidney disease; and patients with an organ transplant are not eligible for treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 13230 |
| C13231 | P13231 | CN13231 | Brentuximab vedotin | Relapsed or Refractory Hodgkin lymphoma  Continuing treatment  Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition; AND  Patient must not be suitable for ASCT for this condition; or  Patient must not be suitable for treatment with multi-agent chemotherapy for this condition; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND  Patient must not receive more than 12 cycles of treatment under this restriction.  The treatment must not exceed a total of 16 cycles of combined initial and continuing treatment in a lifetime. | Compliance with Authority Required procedures |
| 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  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 |
| 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 condition; AND  Patient must not have progressive disease. | Compliance with Authority Required procedures - Streamlined Authority Code 13258 |
| C13259 | P13259 | CN13259 | Brentuximab vedotin | Relapsed or Refractory Hodgkin lymphoma  Initial treatment  Patient must have undergone a primary autologous stem cell transplant (ASCT); AND  Patient must have experienced a relapsed CD30+ Hodgkin lymphoma post ASCT; or  Patient must have experienced a refractory CD30+ Hodgkin lymphoma post ASCT; AND  Patient must not receive more than 4 cycles of treatment under this restriction.  Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.  If the application is submitted through HPOS upload or mail, it must include  (a) a completed authority prescription form; and  (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | Compliance with Authority Required procedures |
| 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 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. | Compliance with Written Authority Required procedures |
| 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  The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS); AND  The condition must have up to 20% marrow blasts according to World Health Organisation (WHO) Classification.  Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations  (a) 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR  (b) 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR  (c) 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR  (d) 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR  (e) Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.  Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations  (a) 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR  (b) 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.  The following information must be provided by the prescriber at the time of application  (a) The patient's International Prognostic Scoring System (IPSS) score.  The following reports must be documented in the patient's medical records  (a) bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and  (b) full blood examination report; and  (c) pathology report detailing the cytogenetics demonstrating intermediate-2 or high-risk disease according to the International Prognostic Scoring System (IPSS).  No more than 3 cycles will be authorised under this restriction in a patient's lifetime. | Compliance with Authority Required procedures |
| 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 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. | Compliance with Written Authority Required procedures |
| 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) 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 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. | Compliance with Authority Required procedures |
| 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  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 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. | Compliance with Authority Required procedures |
| 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 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 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 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. | Compliance with Authority Required procedures |
| C13288 | P13288 | CN13288 | Somatrogon  Somatropin | 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 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 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. | Compliance with Authority Required procedures |
| 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 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 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).  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. | Compliance with Authority Required procedures |
| 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 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). | Compliance with Authority Required procedures |
| 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 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 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 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. | Compliance with Authority Required procedures |
| C13297 | P13297 | CN13297 | Somatrogon | Short stature associated with biochemical growth hormone deficiency  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 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  (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. | Compliance with Authority Required procedures |
| 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 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 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 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. | Compliance with Authority Required procedures |
| 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 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 '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. | Compliance with Authority Required procedures |
| 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  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. | Compliance with Authority Required procedures |
| C13309 | P13309 | CN13309 | Somatrogon  Somatropin | 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  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;  (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. | Compliance with Authority Required procedures |
| 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  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 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. | Compliance with Authority Required procedures |
| 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  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 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. | Compliance with Authority Required procedures |
| 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 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  (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. | Compliance with Authority Required procedures |
| 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; 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 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). | Compliance with Authority Required procedures |
| 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 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. | Compliance with Authority Required procedures |
| C13336 | P13336 | CN13336 | Aflibercept  Dexamethasone  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  (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 |
| 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 |
| C13341 | P13341 | CN13341 | Dexamethasone | Diabetic macular oedema (DMO)  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 diabetic macular oedema; AND  Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment; AND  The condition must be diagnosed by optical coherence tomography; or  The condition must be diagnosed by fluorescein angiography; AND  Patient must have had a cataract removed in the treated eye; or  Patient must be scheduled for cataract surgery in the treated eye; AND  Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; or  Patient must be unsuitable for treatment with VEGF inhibitors; or  Patient must have failed prior treatment with VEGF inhibitors; AND  The treatment must be as monotherapy; or  The treatment must be in combination with laser photocoagulation; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  Authority approval for initial treatment of each eye must be sought.  The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include  (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.  (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 |
| C13346 | P13346 | CN13346 | Somatropin | 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 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 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.  The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND  3. (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; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  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. | Compliance with Authority Required procedures |
| C13350 | P13350 | CN13350 | Somatropin | Short stature and slow growth  Continuing treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category; AND  Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); 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  Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND  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; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. The final adult height (in cm) of the patient's mother and father (where available); AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  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. | Compliance with Authority Required procedures |
| C13352 | P13352 | CN13352 | Somatropin | Short stature and slow growth  Recommencement of treatment  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 had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; 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.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND  3. Recent growth data (height and weight, not older than three months); AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  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. | Compliance with Authority Required procedures |
| C13353 | P13353 | CN13353 | Somatropin | Short stature associated with biochemical growth hormone deficiency  Recommencement of treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with biochemical growth hormone deficiency; AND  Patient must have had a lapse in treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); or  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 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.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND  3. (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 (except for a patient whose chronological age was 2.5 years or less 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 and sex immediately prior to commencing treatment; OR  (c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND  4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  5. Recent growth data (height and weight, not older than three months); AND  6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  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. | Compliance with Authority Required procedures |
| C13355 | P13355 | CN13355 | Somatropin | Short stature and slow growth  Recommencement of treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature and slow growth; AND  Patient must have had a lapse in treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; or  Patient must have had a height at or below the 1st percentile 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:   (i) a height no higher than the 1st percentile for age plus sex at the time of having commenced treatment with this drug, (ii) over the 12 month interval immediately prior to having commenced treatment, a growth velocity no greater than 8 cm/year where the patient had a bone/chronological age of no greater than 2.5 years; 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.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND  3. (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 the patient's chronological age was higher than 2.5 years); OR  (b) Confirmation that the patient has previously received treatment under the indication short stature associated with chronic renal insufficiency, has undergone a renal transplant and a 12 month period of observation following the transplant, and has an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; AND  4. Recent growth data (height and weight, not older than three months); AND  5. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  6. The proprietary name (brand), form and strength of the growth hormone requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  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. | Compliance with Authority Required procedures |
| C13356 | P13356 | CN13356 | Somatropin | 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  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.  The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND  3. 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; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. Confirmation of the patient's maturational or constitutional delay status; AND  6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  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. | Compliance with Authority Required procedures |
| C13359 | P13359 | CN13359 | Somatropin | Short stature and slow growth  Continuing treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature and slow growth; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; or  Patient must have had a height at or below the 1st percentile 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:   (i) a height no higher than the 1st percentile for age plus sex at the time of having commenced treatment with this drug, (ii) over the 12 month interval immediately prior to having commenced treatment, a growth velocity no greater than 8 cm/year where the patient had a bone/chronological age of no greater than 2.5 years; 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.  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 maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND  3. (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 the patient's chronological age was higher than 2.5 years); OR  (b) Confirmation that the patient has previously received treatment under the indication **short stature associated with chronic renal**  **insufficiency**, has undergone a renal transplant and a 12 month period of observation following the transplant, and has an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; AND  4. 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; AND  5. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  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. | Compliance with Authority Required procedures |
| C13360 | P13360 | CN13360 | Somatropin | Short stature associated with biochemical growth hormone deficiency  Recommencement of treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; 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.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND  3. Recent growth data (height and weight, not older than three months); AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  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. | Compliance with Authority Required procedures |
| C13363 | P13363 | CN13363 | Somatropin | Short stature associated with biochemical growth hormone deficiency  Continuing treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category; AND  Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); 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.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND  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; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. The final adult height (in cm) of the patient's mother and father (where available); AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  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. | Compliance with Authority Required procedures |
| C13364 | P13364 | CN13364 | Somatropin | Short stature associated with biochemical growth hormone deficiency  Continuing treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with biochemical growth hormone deficiency; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); or  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 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.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND  3. (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 (except for a patient whose chronological age was 2.5 years or less 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 and sex immediately prior to commencing treatment; OR  (c) Confirmation that the patient has previously received treatment under the indication *risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants* and has reached or surpassed 5 years of age (chronological); AND  4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  5. 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; AND  6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  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. | Compliance with Authority Required procedures |
| C13367 | P13367 | CN13367 | Somatropin | 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 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 8 cm per year or less if the patient has a bone 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  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.  The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND  3. (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; AND  4. A bone age result performed within the last 12 months; AND  5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  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. | Compliance with Authority Required procedures |
| C13368 | P13368 | CN13368 | Somatropin | Short stature associated with biochemical growth hormone deficiency  Recommencement of treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; 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.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND  3. Recent growth data (height and weight, not older than three months); AND  4. A bone age result performed within the last 12 months; AND  5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  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. | Compliance with Authority Required procedures |
| C13378 | P13378 | CN13378 | Nintedanib  Pirfenidone | Idiopathic pulmonary fibrosis  Initial treatment 1 - new patient  The condition must be diagnosed through a multidisciplinary team; AND  Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months; AND  Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height; AND  Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7; AND  Patient must not have had an acute respiratory infection at the time of FVC measurement; AND  Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%; AND  Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Must be treated by a medical practitioner who is either:   (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician; AND  Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications:   (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND  Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications:   (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND  Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following:   (i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement.  A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.  Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records.  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) | Compliance with Written Authority Required procedures |
| C13380 | P13380 | CN13380 | Nintedanib  Pirfenidone | Idiopathic pulmonary fibrosis  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  Must be treated by a medical practitioner who is either:   (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician; AND  Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications:   (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND  Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications:   (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis. | Compliance with Authority Required procedures |
| C13381 | P13381 | CN13381 | Nintedanib  Pirfenidone | Idiopathic pulmonary fibrosis  Initial treatment 2 - change or recommencement of treatment  Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Must be treated by a medical practitioner who is either:   (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician; AND  Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications:   (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND  Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications:   (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis. | Compliance with Authority Required procedures |
| 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.  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 |
| C13387 | P13387 | CN13387 | Aflibercept  Dexamethasone  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 |
| C13388 | P13388 | CN13388 | Aflibercept  Faricimab  Ranibizumab | Diabetic macular oedema (DMO)  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 diabetic macular oedema; AND  Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment; AND  The condition must be diagnosed by optical coherence tomography; or  The condition must be diagnosed by fluorescein angiography; AND  The treatment must be as monotherapy; or  The treatment must be in combination with laser photocoagulation; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  Authority approval for initial treatment of each eye must be sought.  The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include  (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.  (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 |
| 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 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. | Compliance with Written Authority Required procedures |
| 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 |
| C13393 | P13393 | CN13393 | Somatropin | Short stature associated with biochemical growth hormone deficiency  Continuing treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category; AND  Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); 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.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND  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; AND  4. A bone age result performed within the last 12 months; AND  5. The final adult height (in cm) of the patient's mother and father (where available); AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  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. | Compliance with Authority Required procedures |
| C13401 | P13401 | CN13401 | Nintedanib | Progressive fibrosing Interstitial lung disease  Initial treatment  The condition must be diagnosed through a multidisciplinary team; AND  The condition must have chest imaging through high resolution computed tomography (HRCT) that is no older than 12 months, to support the diagnosis of the PBS indication; AND  The condition must display, through HRCT, an affected area of no less than 10% (after rounding to the nearest multiple of 5); AND  Patient must have a current (no older than 2 years) forced vital capacity (FVC) measurement of no less than 45% predicted, adjusted for each of:   (i) age, (ii) gender, (iii) height; AND  The condition must be of a progressive nature, observed by, in the 2 years leading up to this authority application, any of:   (i) a worsening in relative FVC% predicted measurement of no less than 10%, (ii) a worsening in relative FVC% predicted measurement in the range 5-10%, combined with worsening of respiratory symptoms, (iii) a worsening in relative FVC% predicted measurement in the range 5-10%, combined with increases in fibrosis observed on HRCT; document at least one of (i) to (iii) in the patient's medical records; AND  Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7; AND  Patient must not have had an acute respiratory infection at the time of FVC measurement; AND  Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin that is both:   (i) at least 30% predicted, (ii) no greater than 80% predicted; AND  The condition must not be interstitial lung disease due to idiopathic pulmonary fibrosis (apply under the correct PBS listing if it is); AND  The condition must not be due to reversible causes (e.g. drug toxicity); AND  Must be treated by a medical practitioner who is either:   (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician; AND  Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications:   (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND  Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications:   (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND  Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following:   (i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement.  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)  A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.  Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records. | Compliance with Written Authority Required procedures |
| C13402 | P13402 | CN13402 | Aflibercept  Faricimab  Ranibizumab | 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 previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND  The treatment must be as monotherapy; or  The treatment must be in combination with laser photocoagulation; AND  The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 13402 |
| C13406 | P13406 | 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 |
| C13412 | P13412 | CN13412 | Nintedanib | Progressive fibrosing Interstitial lung disease  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Must be treated by a medical practitioner who is either:   (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician; AND  Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications:   (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND  Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications:   (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis. | Compliance with Authority Required procedures |
| C13417 | P13417 | CN13417 | Somatropin | Short stature associated with biochemical growth hormone deficiency  Continuing treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with biochemical growth hormone deficiency; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); or  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 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.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND  3. (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 (except for a patient whose chronological age was 2.5 years or less 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 and sex immediately prior to commencing treatment; OR  (c) Confirmation that the patient has previously received treatment under the indication *risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants* and has reached or surpassed 5 years of age (chronological); AND  4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  5. 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; AND  6. A bone age result performed within the last 12 months; AND  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  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. | Compliance with Authority Required procedures |
| C13418 | P13418 | CN13418 | Somatropin | Short stature associated with biochemical growth hormone deficiency  Recommencement of treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with biochemical growth hormone deficiency; AND  Patient must have had a lapse in treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); or  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 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.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND  3. (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 (except for a patient whose chronological age was 2.5 years or less 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 and sex immediately prior to commencing treatment; OR  (c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND  4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  5. Recent growth data (height and weight, not older than three months); AND  6. A bone age result performed within the last 12 months; AND  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  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. | 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 |
| 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 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. | Compliance with Written Authority Required procedures |
| C13424 | P13424 | CN13424 | Aflibercept  Faricimab | 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 |
| 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  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. | Compliance with Written Authority Required procedures |
| 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 |
| 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 |
| C13431 | P13431 | CN13431 | Pembrolizumab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Initial treatment - 3 weekly treatment regimen  Patient must not have previously been treated for this condition in the metastatic setting; or  The condition must have progressed after treatment with tepotinib; AND  Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND  Patient must have a WHO performance status of 0 or 1; AND  The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND  The treatment must not exceed a total of 7 doses under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 13431 |
| 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 |
| C13433 | P13433 | CN13433 | Nivolumab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Initial combination treatment (with ipilimumab) as first-line drug therapy  The condition must be squamous type non-small cell lung cancer (NSCLC); AND  Patient must not have previously been treated for this condition in the metastatic setting; or  The condition must have progressed after treatment with tepotinib; AND  Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND  Patient must have a WHO performance status of 0 or 1; AND  The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND  The treatment must be in combination with platinum-based chemotherapy for the first two cycles; AND  The treatment must be in combination with ipilimumab. | Compliance with Authority Required procedures - Streamlined Authority Code 13433 |
| 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 |
| C13436 | P13436 | CN13436 | Pembrolizumab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Initial treatment - 6 weekly treatment regimen  Patient must not have previously been treated for this condition in the metastatic setting; or  The condition must have progressed after treatment with tepotinib; AND  Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND  Patient must have a WHO performance status of 0 or 1; AND  The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND  The treatment must not exceed a total of 4 doses under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 13436 |
| 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 |
| 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  Patient must have a WHO performance status of 0 or 1; AND  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND  The condition must have progressed on or after prior platinum based chemotherapy. or  The condition must have progressed after treatment with tepotinib. | Compliance with Authority Required procedures - Streamlined Authority Code 13443 |
| 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 |
| C13448 | P13448 | CN13448 | Atezolizumab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Initial treatment 1  Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy; AND  The condition must be non-squamous type non-small cell lung cancer (NSCLC); AND  Patient must not have previously been treated for this condition in the metastatic setting; or  The condition must have progressed after treatment with tepotinib; AND  Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND  Patient must have a WHO performance status of 0 or 1; AND  The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material. | Compliance with Authority Required procedures - Streamlined Authority Code 13448 |
| C13451 | 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-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 13451 |
| C13532 | P13532 | CN13532 | Etanercept | Severe psoriatic arthritis  Initial treatment - Initial 1 (new patient)  Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND  Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or  Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be at least 18 years of age;  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.  Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.  Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.  The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application  an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and  either  (a) an active joint count of at least 20 active (swollen and tender) joints; or  (b) at least 4 active joints from the following list of major joints  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C13533 | P13533 | CN13533 | Etanercept | Severe psoriatic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be at least 18 years of age;  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.  An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C13538 | P13538 | CN13538 | Etanercept | Severe chronic plaque psoriasis  Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be at least 18 years of age;  Must be treated by a dermatologist.  The most recent PASI assessment must be no more than 1 month old at the time of application.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.  It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.  To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
| 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:   (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be at least 18 years of age;  Must be treated by a dermatologist.  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
| C13558 | P13558 | CN13558 | Lorlatinib | 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 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. | Compliance with Authority Required procedures |
| 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 |
| C13562 | P13562 | CN13562 | Vericiguat | Chronic heart failure  Initial treatment  Must be treated by a cardiologist; or  Must be treated by a medical practitioner who has been directed to prescribe this medicine by a cardiologist; AND  Patient must be symptomatic with NYHA classes II, III or IV; AND  Patient must have a documented left ventricular ejection fraction (LVEF) of less than 45%; AND  The condition must be stabilised following a decompensation event that required at least one of:   (i) hospitalisation in the past 6 months, (ii) intravenous diuretic therapy in the past three months; AND  Patient must not have clinical signs of fluid overload; AND  Patient must not have received intravenous treatment for fluid overload in the previous 24 hours; AND  Patient must not have a systolic blood pressure less than 100 mmHg; 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 |
| C13593 | P13593 | CN13593 | Etanercept | 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 a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND  The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be at least 18 years of age.  Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.  If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.  An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C13598 | P13598 | CN13598 | Etanercept | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be at least 18 years of age;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to 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.  Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.  To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.  The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| 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  Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; or  Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle; AND  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND  The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be at least 18 years of age.  Active joints are defined as  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  All measurements must be no more than 4 weeks old at the time of this application.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C13602 | P13602 | 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. 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  (iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.  Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.  All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.  If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.  If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.  Details of the accepted toxicities including severity can be found on the Services Australia website.  Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.  An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C13609 | P13609 | 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;  Patient must be at least 18 years of age.  The authority application must be made in writing and must include  (1) two completed authority prescription forms; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  Evidence of intestinal inflammation includes  (i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or  (ii) faeces higher than normal lactoferrin or calprotectin level; or  (iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.  Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.  Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C13612 | P13612 | 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 necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
| 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.  For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 13625 |
| C13646 | P13646 | CN13646 | Etanercept | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be at least 18 years of age;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to 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.  Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.  To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C13647 | P13647 | CN13647 | Etanercept | Severe chronic plaque psoriasis  Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:   (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be at least 18 years of age;  Must be treated by a dermatologist.  The most recent PASI assessment must be no more than 1 month old at the time of application.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.  It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.  To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.  The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
| 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  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C13681 | P13681 | 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 application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:   (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; or  Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs:   (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; or  Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of:   (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; or  Patient must have a contraindication/severe intolerance to each of:   (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be at least 18 years of age.  If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.  The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.  The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.  If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.  The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application  an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either  (a) an active joint count of at least 20 active (swollen and tender) joints; or  (b) at least 4 active joints from the following list  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measurements must be no more than 4 weeks old at the time of initial application.  If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C13694 | P13694 | 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.  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| 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  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. | Compliance with Authority Required procedures - Streamlined Authority Code 13718 |
| 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 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. | Compliance with Authority Required procedures - Streamlined Authority 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 |
| 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  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 13732 |
| 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  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 13736 |
| 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  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 13741 |
| 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. |  |
| C13752 | P13752 | CN13752 | Daratumumab | Relapsed and/or refractory multiple myeloma  Initial treatment as second-line drug therapy for weeks 1 to 9 (administered once weekly)  The condition must be confirmed by a histological diagnosis; AND  The treatment must be in combination with bortezomib and dexamethasone; AND  Patient must have progressive disease after only one prior therapy (i.e. use must be as second-line drug therapy; use as third-line drug therapy or beyond is not PBS-subsidised); AND  Patient must be undergoing treatment with this drug in one of the following situations:   (i) for the first time, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), (ii) changing the drug's form (intravenous/subcutaneous) within the first 9 weeks of treatment for the same PBS indication.  Progressive disease is defined as at least 1 of the following  (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or  (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or  (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or  (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or  (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or  (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or  (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).  Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.  Details of the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.  Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records  (a) the level of serum monoclonal protein; or  (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or  (c) the serum level of free kappa and lambda light chains; or  (d) bone marrow aspirate or trephine; or  (e) if present, the size and location of lytic bone lesions (not including compression fractures); or  (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or  (g) if present, the level of hypercalcaemia, corrected for albumin concentration.  As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.  A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.  A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease. | Compliance with Authority Required procedures |
| 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 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 |
| 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  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. | Compliance with Authority Required procedures - 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 13867 |
| 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:   (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. | Compliance with Authority Required procedures - Streamlined Authority Code 13876 |
| 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 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. | Compliance with Authority Required procedures |
| 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 |
| C13886 | P13886 | CN13886 | Calcitonin salmon | Hypercalcaemia  The treatment must be initiated in a hospital; AND  The treatment must be for a patient who cannot tolerate bisphosphonates due to kidney disease. | Compliance with Authority Required procedures |
| C13887 | P13887 | CN13887 | Methyldopa | Hypertension  Patient must be pregnant. | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 13892 |
| 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:   (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. | Compliance with Authority Required procedures |
| 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  (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. | Compliance with Authority Required procedures - Streamlined Authority Code 13906 |
| 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 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 13907 |
| 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-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. | Compliance with Authority Required procedures - Streamlined Authority Code 13911 |
| C13912 | P13912 | CN13912 | Sapropterin | Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)  Subsequent continuing  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. | Compliance with Authority Required procedures |
| C13913 | P13913 | CN13913 | Calcitonin salmon | Symptomatic Paget disease of bone  The treatment must be for a patient who cannot tolerate bisphosphonates due to kidney disease. | Compliance with Authority Required procedures |
| 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  Patient must be undergoing first continuing treatment with this drug, demonstrating either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%. or  Patient must be undergoing subsequent continuing treatment with this drug, demonstrating a 12-month response of either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%.  A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 13923 |
| C13925 | P13925 | 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 BCR-ABL level of less than 1% after a minimum of 12 months therapy; OR  2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph+ cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR  3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR  4. Development of accelerated phase in a patient previously prescribed a TKI inhibitor for any phase of chronic myeloid leukaemia; OR  5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during TKI therapy in patients with accelerated phase chronic myeloid leukaemia.  Accelerated phase is defined by the presence of 1 or more of the following  1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or  2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or  3. Peripheral basophils greater than or equal to 20%; or  4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or  5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).  The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include  (i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or  (ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and  (iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation; and  (iv) where there has been a loss of response to imatinib or dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.  All reports must be documented in the patient's medical records.  If the application is submitted through HPOS form upload or mail, it must include  (i) A completed authority prescription form; and  (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib, ponatinib or asciminib at any one time and must not be receiving concomitant interferon alfa therapy  Up to a maximum of 18 months of treatment may be authorised under this initial restriction. | Compliance with Written Authority Required procedures |