

National Health (Listing of Pharmaceutical Benefits) Instrument 2012 (PB 71 of 2012)

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

National Health Act 1953

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This compilation is in 6 volumes

Volume 1: sections 1–26 and Schedule 1 (A–C)

Volume 2: Schedule 1 (D–K)

Volume 3: Schedule 1 (L–P)

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

Volume 5: Schedule 4 (Part 1: A–R)

**Volume 6: Schedule 4 (Part 1: S–Z, Part 3), 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 2012 (PB 71 of 2012)* that shows the text of the law as amended and in force on 1 July 2020 (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 Legislation 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 series page on the Legislation 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 series page on the Legislation 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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.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 and conditions codes

(sections 10‑15,17, 18, 20 and 21)

Part 1—Circumstances, purposes and conditions

| **Listed Drug** | **Circumstances Code** | **Purposes Code** | **Conditions Code** | **Circumstances and Purposes** | **Authority Requirements (part of Circumstances; or Conditions)** |
| --- | --- | --- | --- | --- | --- |
| Sacubitril with valsartan | C6915 |  |  | Chronic heart failure Patient must be symptomatic with NYHA classes II, III or IV; AND Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%; AND Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated; AND Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist. | Compliance with Authority Required procedures - Streamlined Authority Code 6915 |
| Safinamide | C8624 |  |  | Parkinson disease  The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination. |  |
| Salbutamol | C6367 |  |  | Bronchospasm Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug. |  |
| C6815 |  |  | Asthma Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer. |  |
| C6825 |  |  | Chronic obstructive pulmonary disease (COPD) Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer. |  |
| Salmeterol | C6355 |  |  | Asthma Patient must experience frequent episodes of the condition; AND Patient must be currently receiving treatment with oral corticosteroids; OR Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids. |  |
| Sapropterin | C8898 | P8898 |  | Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU) Initial treatment - responsiveness testing Must be treated by a metabolic physician. Patient must not have previously received PBS-subsidised treatment with this drug for this condition; 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. Patient must be under 18 years of age. 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 |
|  | C8926 | P8926 |  | 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. 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. Patient must have been under 18 years of age at the time treatment with this drug was initiated for this condition. 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 |
|  | C10076 | P10076 |  | Hyperphenylalaninaemia Initial treatment Must be treated by a metabolic physician. Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency. Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured. | Compliance with Authority Required procedures |
|  | C10355 | P10355 |  | Hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency 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. Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition. Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured. | Compliance with Authority Required procedures |
|  | C10364 | P10364 |  | 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. 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. Patient must have been under 18 years of age at the time treatment with this drug was initiated for this condition. | Compliance with Authority Required procedures |
|  | C10390 | P10390 |  | Hyperphenylalaninaemia 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. Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition. Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured. | Compliance with Authority Required procedures |
|  | C10391 | P10391 |  | Hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency Initial treatment Must be treated by a metabolic physician. Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency. Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured. | Compliance with Authority Required procedures |
| Saquinavir | C4454 |  |  | HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 4454 |
| C4512 |  |  | HIV infection Initial Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 4512 |
| Saxagliptin | C6346 |  |  | Diabetes mellitus type 2 The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 6346 |
| C6363 |  |  | Diabetes mellitus type 2 The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 6363 |
| C7505 |  |  | Diabetes mellitus type 2 Continuing treatment The treatment must be in combination with metformin; AND The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7505 |
| C7541 |  |  | Diabetes mellitus type 2 Initial treatment The treatment must be in combination with metformin; AND The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and an SGLT2 inhibitor; OR Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin. The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 7541 |
| Saxagliptin with dapagliflozin | C7524 |  |  | Diabetes mellitus type 2 Initial treatment The treatment must be in combination with metformin; AND Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a dipeptidyl peptidase 4 inhibitor (gliptin) or a sodium-glucose co-transporter 2 (SGLT2) inhibitor; OR Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin. The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 7524 |
| C7556 |  |  | Diabetes mellitus type 2 Continuing treatment The treatment must be in combination with metformin; AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7556 |
| Saxagliptin with metformin | C6333 |  |  | Diabetes mellitus type 2 Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. | Compliance with Authority Required procedures - Streamlined Authority Code 6333 |
| C6335 |  |  | Diabetes mellitus type 2 Continuing Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and saxagliptin. | Compliance with Authority Required procedures - Streamlined Authority Code 6335 |
| C6344 |  |  | Diabetes mellitus type 2 The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. | Compliance with Authority Required procedures - Streamlined Authority Code 6344 |
| C7507 |  |  | Diabetes mellitus type 2 Initial treatment The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and an SGLT2 inhibitor for this condition; OR Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin. The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 7507 |
| C7530 |  |  | Diabetes mellitus type 2 Continuing treatment The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7530 |
| Secukinumab | C6696 | P6696 |  | Severe chronic plaque psoriasis Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND The treatment must be as systemic monotherapy (other than methotrexate). Must be treated by a dermatologist. | Compliance with Authority Required procedures |
|  | C8830 | P8830 |  | Severe chronic plaque psoriasis Continuing treatment, Whole body Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C8831 | P8831 |  | Severe chronic plaque psoriasis Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must be as systemic monotherapy (other than methotrexate); AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a dermatologist. | Compliance with Authority Required procedures |
|  | C8837 | P8837 |  | 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 aged 18 years or older. 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 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 |
|  | C8851 | P8851 |  | 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 aged 18 years or older. 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 |
|  | C8867 | P8867 |  | Severe chronic plaque psoriasis Initial treatment - Initial 1, Face, hand, foot (new patient) Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 1 month old at the time of application. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to 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 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 |
|  | C8892 | P8892 |  | Severe chronic plaque psoriasis Continuing treatment, Face, hand, foot Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C8905 | P8905 |  | Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 1 month old at the time of application. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to 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 |
|  | C9063 | P9063 |  | Severe psoriatic arthritis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. | Compliance with Authority Required procedures |
|  | C9064 | P9064 |  | Severe psoriatic arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. | Compliance with Authority Required procedures |
|  | C9069 | P9069 |  | Severe psoriatic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C9078 | P9078 |  | Severe psoriatic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C9105 | P9105 |  | Severe psoriatic arthritis Continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C9155 | P9155 |  | Severe psoriatic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. 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 |
|  | C9414 | P9414 |  | Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. 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 |
|  | C9428 | P9428 |  | Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment 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 |
|  | C9429 | P9429 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |
|  | C9430 | P9430 |  | Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. 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 |
|  | C9431 | P9431 |  | Ankylosing spondylitis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |
|  | C9503 | P9503 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application. Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form; and (iii) a completed Exercise Program Self Certification Form included in the 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 |
|  | C9872 | P9872 |  | Severe chronic plaque psoriasis Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or 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 |
|  | C9901 | P9901 |  | Severe chronic plaque psoriasis Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or 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 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 |
| Selegiline | C5338 |  |  | Late stage Parkinson disease The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination. |  |
| Semaglutide | C5478 |  |  | Diabetes mellitus type 2 The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 5478 |
|  | C5500 |  |  | Diabetes mellitus type 2 The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR Patient must not have tolerated a combination of metformin and a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 5500 |
| Sertraline | C4755 |  |  | Major depressive disorders |  |
| C6277 |  |  | Obsessive-compulsive disorder |  |
| C6289 |  |  | Panic disorder The treatment must be for use when other treatments have failed; OR The treatment must be for use when other treatments are inappropriate. |  |
| Sevelamer | C5491 |  |  | Hyperphosphataemia Maintenance following initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease. | Compliance with Authority Required procedures - Streamlined Authority Code 5491 |
| C5530 |  |  | Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease. | Compliance with Authority Required procedures - Streamlined Authority Code 5530 |
|  | C9762 |  |  | Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease. | Compliance with Authority Required procedures - Streamlined Authority Code 9762 |
| Silver sulfadiazine | C6345 |  |  | Stasis ulcers |  |
| C6362 |  |  | Infection Prevention and treatment The condition must be in partial or full skin thickness loss due to burns; OR The condition must be in partial or full skin thickness loss due to epidermolysis bullosa. |  |
| Simvastatin |  | P7598 |  | For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |
| Sirolimus |  | P5795 | CN5795 | Management of renal allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 5795 |
|  |  | P9914 | CN9914 | Management of renal allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 9914 |
| Sitagliptin | C6346 |  |  | Diabetes mellitus type 2 The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 6346 |
| C6363 |  |  | Diabetes mellitus type 2 The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 6363 |
| C6376 |  |  | Diabetes mellitus type 2 The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 6376 |
|  | C7505 |  |  | Diabetes mellitus type 2 Continuing treatment The treatment must be in combination with metformin; AND The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7505 |
|  | C7541 |  |  | Diabetes mellitus type 2 Initial treatment The treatment must be in combination with metformin; AND The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and an SGLT2 inhibitor; OR Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin. The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 7541 |
| Sitagliptin with metformin | C6333 |  |  | Diabetes mellitus type 2 Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. | Compliance with Authority Required procedures - Streamlined Authority Code 6333 |
| C6334 |  |  | Diabetes mellitus type 2 Continuing Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and sitagliptin. | Compliance with Authority Required procedures - Streamlined Authority Code 6334 |
| C6344 |  |  | Diabetes mellitus type 2 The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. | Compliance with Authority Required procedures - Streamlined Authority Code 6344 |
| C6443 |  |  | Diabetes mellitus type 2 The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 6443 |
|  | C7507 |  |  | Diabetes mellitus type 2 Initial treatment The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and an SGLT2 inhibitor for this condition; OR Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin. The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 7507 |
|  | C7530 |  |  | Diabetes mellitus type 2 Continuing treatment The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7530 |
| Sodium acid phosphate | C5089 |  |  | Hypophosphataemic rickets | Compliance with Authority Required procedures - Streamlined Authority Code 5089 |
| C5095 |  |  | Familial hypophosphataemia | Compliance with Authority Required procedures - Streamlined Authority Code 5095 |
| C5114 |  |  | Vitamin D-resistant rickets | Compliance with Authority Required procedures - Streamlined Authority Code 5114 |
| C5123 |  |  | Hypercalcaemia | Compliance with Authority Required procedures - Streamlined Authority Code 5123 |
| Sodium phenylbutyrate | C9888 |  |  | Urea cycle disorders Grandfathered treatment Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2019. An increase in the maximum quantity will be authorised to provide for up to one month's supply at a dose of up to 600 mg/kg/day in patients weighing less than 20 kg and up to 13 g/m 2 /day in patients weighing more than 20 kg. | Compliance with Authority Required procedures - Streamlined Authority Code 9888 |
|  | C9919 |  |  | Urea cycle disorders Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition. An increase in the maximum quantity will be authorised to provide for up to one month's supply at a dose of up to 600 mg/kg/day in patients weighing less than 20 kg and up to 13 g/m 2 /day in patients weighing more than 20 kg. | Compliance with Authority Required procedures - Streamlined Authority Code 9919 |
|  | C9993 |  |  | Urea cycle disorders Initial treatment Patient must have elevated ammonia levels that are not controlled with diet alone and other adjunct care alone. An increase in the maximum quantity will be authorised to provide for up to one month's supply at a dose of up to 600 mg/kg/day in patients weighing less than 20 kg and up to 13 g/m 2 /day in patients weighing more than 20 kg. | Compliance with Authority Required procedures - Streamlined Authority Code 9993 |
| Sofosbuvir | C5969 | P5969 |  | Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 12 weeks. | Compliance with Authority Required procedures |
| C5972 | P5972 |  | Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 24 weeks. | Compliance with Authority Required procedures |
| Sofosbuvir with velpatasvir | C5969 |  |  | Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 12 weeks. | Compliance with Authority Required procedures |
| Sofosbuvir with velpatasvir and voxilaprevir | C10248 |  |  | Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 12 weeks. The application must include details of the prior treatment regimen containing an NS5A inhibitor. | Compliance with Authority Required procedures |
| Somatropin | C5146 |  |  | 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 diabetes mellitus; 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. 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. 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. | Compliance with Written Authority Required procedures |
| C5147 |  |  | Short stature associated with Turner syndrome Recommencement of treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome 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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 diabetes mellitus; 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 female and must not have a bone age of 13.5 years or more; AND Patient must be female and must not have a height greater than or equal to 155.0cm. 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. 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. | Compliance with Written Authority Required procedures |
| C5151 |  |  | Short stature associated with Turner syndrome Continuing treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category; AND Patient must not have been on the maximum dose of 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/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 diabetes mellitus; 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 a bone age of 13.5 years or greater; AND Patient must not have a height greater than or equal to 155.0 cm. Patient must be aged 3 years or older. 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 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. | Compliance with Written Authority Required procedures |
| C5158 |  |  | Short stature associated with Turner syndrome Initial treatment 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. Patient must have a current height at or below the 95thpercentile for age on the Turner syndrome growth curve for girls; AND Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female; AND Patient must not have diabetes mellitus; 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 not have a bone age of 2.5 years or less; AND Patient must not have a height greater than or equal to 155.0 cm; AND Patient must not have a bone age of 13.5 years or greater. Patient must be aged 3 years or older. 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) at intervals no greater than six months. The most recent data must not be older than three months; OR (b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). 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. Confirmation that the patient has diagnostic results consistent with Turner syndrome; 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. | Compliance with Written Authority Required procedures |
| C5165 |  |  | Growth retardation secondary to an intracranial lesion, or cranial irradiation Recommencement of treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation 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 diabetes mellitus; 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. 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. Patient must be aged 3 years or older. 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. | Compliance with Written Authority Required procedures |
| C5166 |  |  | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants Recommencement of treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants 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 diabetes mellitus; 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 a chronological age of 5 years or greater. 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. Patient must be aged 3 years or older. 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. | Compliance with Written Authority Required procedures |
| C5167 |  |  | Short stature associated with Turner syndrome Recommencement of treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature assciated with Turner syndrome; 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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment; AND Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female; AND Patient must not have diabetes mellitus; 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 a bone age of 2.5 years or less; AND Patient must not have a height greater than or equal to 155.0 cm; AND Patient must not have a bone age of 13.5 years or greater. 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. Patient must be aged 3 years or older. 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 height measurement from immediately prior to commencement of growth hormone treatment; AND 4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; 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 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. | Compliance with Written Authority Required procedures |
| C5190 |  |  | Short stature associated with Turner syndrome Continuing treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome; AND The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment; AND Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female; AND Patient must not have diabetes mellitus; 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 a bone age of 2.5 years or less; AND Patient must not have a bone age of 13.5 years or greater; AND Patient must not have a height greater than or equal to 155.0 cm. 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. 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 height measurement from immediately prior to commencement of growth hormone treatment; AND 4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; 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. | Compliance with Written Authority Required procedures |
| C5230 |  |  | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants Continuing treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants; 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 a chronological age of less than 2 years; AND Patient must have a documented clinical risk of hypoglycaemia; AND Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND Patient must not have diabetes mellitus; 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. 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. 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. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND 4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; 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. 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. | Compliance with Written Authority Required procedures |
| C5236 |  |  | Short stature associated with Turner syndrome Continuing treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome; AND The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment; AND Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female; AND Patient must not have diabetes mellitus; 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 a bone age of 2.5 years or less; AND Patient must not have a bone age of 13.5 years or greater; AND Patient must not have a height greater than or equal to 155.0 cm. Patient must be aged 3 years or older. 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. 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 height measurement from immediately prior to commencement of growth hormone treatment; AND 4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; 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. | Compliance with Written Authority Required procedures |
| C5239 |  |  | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants Initial treatment 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. Patient must have a chronological age of less than 2 years; AND Patient must have a documented clinical risk of hypoglycaemia; AND Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND Patient must not have diabetes mellitus; 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. 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. Recent growth data (height and weight, not older than three months); AND 4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND 5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; 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. | Compliance with Written Authority Required procedures |
| C5247 |  |  | Biochemical growth hormone deficiency and precocious puberty Recommencement of treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty 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 be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND Patient must not have diabetes mellitus; 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. 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. Patient must be aged 3 years or older. 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. | Compliance with Written Authority Required procedures |
| C5285 |  |  | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth Recommencement of treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven 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 diabetes mellitus; 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. 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. Patient must be aged 3 years or older. 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. | Compliance with Written Authority Required procedures |
| C5286 |  |  | Short stature associated with chronic renal insufficiency Recommencement of treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency 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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 diabetes mellitus; 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 undergone a renal transplant within the 12 month period immediately prior to the date of application; AND Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2; 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. 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. Patient must be aged 3 years or older. 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. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2; AND 6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; 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. If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2prescribers should seek reclassification to the indication short stature and slow growth. | Compliance with Written Authority Required procedures |
| C5299 |  |  | Short stature associated with Turner syndrome Continuing treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category; AND Patient must not have been on the maximum dose of 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/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 diabetes mellitus; 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 a bone age of 13.5 years or greater; AND Patient must not have a height greater than or equal to 155.0 cm. 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 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. | Compliance with Written Authority Required procedures |
| C5302 |  |  | Short stature associated with Turner syndrome Recommencement of treatment as a reclassified patient 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. Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome; 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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment; AND Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female; AND Patient must not have diabetes mellitus; 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 a bone age of 2.5 years or less; AND Patient must not have a height greater than or equal to 155.0 cm; AND Patient must not have a bone age of 13.5 years or greater. 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 height measurement from immediately prior to commencement of growth hormone treatment; AND 4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; 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 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. | Compliance with Written Authority Required procedures |
| C5318 |  |  | Short stature associated with Turner syndrome Recommencement of treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome 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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 diabetes mellitus; 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 female and must not have a bone age of 13.5 years or more; AND Patient must be female and must not have a height greater than or equal to 155.0cm. 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. Patient must be aged 3 years or older. 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. | Compliance with Written Authority Required procedures |
| C5319 |  |  | Short stature due to short stature homeobox (SHOX) gene disorders Recommencement of treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders 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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma; AND Patient must not have diabetes mellitus; AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); 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. Patient must be aged 3 years or older. 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. 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. | Compliance with Written Authority Required procedures |
| C5352 |  |  | 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 diabetes mellitus; 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. 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. Patient must be aged 3 years or older. 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. | Compliance with Written Authority Required procedures |
| C5382 |  |  | Short stature associated with Turner syndrome Initial treatment 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. Patient must have a current height at or below the 95thpercentile for age on the Turner syndrome growth curve for girls; AND Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female; AND Patient must not have diabetes mellitus; 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 not have a bone age of 2.5 years or less; AND Patient must not have a height greater than or equal to 155.0cm; AND Patient must not have a bone age of 13.5 years or greater. 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) at intervals no greater than six months. The most recent data must not be older than three months; OR (b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). 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. Confirmation that the patient has diagnostic results consistent with Turner syndrome; 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. | Compliance with Written Authority Required procedures |
| C8334 |  |  | Short stature and slow growth Initial treatment Patient must have a current height at or below the 1stpercentile for age and sex; AND Patient must have a growth velocity below the 25thpercentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); AND Patient must not have diabetes mellitus; 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 not have a bone age of 2.5 years or less; 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. 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. 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; 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 1stadult 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. | Compliance with Written Authority Required procedures |
| C8335 |  |  | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth Initial treatment Patient must have a structural lesion that is not neoplastic; OR Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion; 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 have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies); AND Patient must have hypothalamic obesity; AND Patient must have a growth velocity above the 25thpercentile 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 greater than 14 cm per year if the patient has a chronological age of 2 years or less; OR Patient must have an annual growth velocity of greater than 8 cm per year if the patient has a bone or chronological age of 2.5 years or less; AND Patient must not have diabetes mellitus; 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. 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. 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. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND 7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND 8. Confirmation that the patient has hypothalamic obesity; AND 9. 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. Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced. | Compliance with Written Authority Required procedures |
| C8336 |  |  | Short stature due to short stature homeobox (SHOX) gene disorders Initial treatment Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma; AND Patient must have a current height at or below the 1stpercentile for age and sex; AND Patient must have a growth velocity below the 25thpercentile 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 14 cm per year or less if the patient has a chronological age of 2 years or less; 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 diabetes mellitus; AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); 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 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 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. 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. 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 that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND 6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; 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. | Compliance with Written Authority Required procedures |
| C8337 |  |  | 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 1stpercentile for age and sex; OR Patient must have a current height above the 1stand at or below the 25thpercentiles for age and sex and a growth velocity below the 25thpercentile 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 1stand at or below the 25thpercentiles 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 1stand at or below the 25thpercentiles 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 diabetes mellitus; 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. 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. 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 1stpercentile 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. | Compliance with Written Authority Required procedures |
| C8338 |  |  | Short stature associated with chronic renal insufficiency Initial treatment 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. Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant; AND Patient must have a current height at or below the 1stpercentile for age and sex; OR Patient must have a current height above the 1stand at or below the 25thpercentiles for age and sex and a growth velocity less than or equal to the 25thpercentile 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 1stand at or below the 25thpercentiles 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 1stand at or below the 25thpercentiles 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 diabetes mellitus; 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 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. Patient must be prepubertal. 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 1stpercentile 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. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2; AND 6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; 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. | Compliance with Written Authority Required procedures |
| C8342 |  |  | 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 1stpercentile for age and sex; OR Patient must have a current height above the 1stand at or below the 25thpercentiles for age and sex and a growth velocity below the 25thpercentile 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 1stand at or below the 25thpercentiles 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 diabetes mellitus; 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. Patient must be aged 3 years or older. 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. 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 1stpercentile 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. | Compliance with Written Authority Required procedures |
| C8343 |  |  | Growth retardation secondary to an intracranial lesion, or cranial irradiation Initial treatment Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; 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 have a current height at or below the 1stpercentile for age and sex; OR Patient must have a current height above the 1stpercentile 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 1stpercentile 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 1stpercentile 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 diabetes mellitus; 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. 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. 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 1stpercentile 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. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; 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. | Compliance with Written Authority Required procedures |
| C8347 |  |  | Short stature associated with chronic renal insufficiency Initial treatment Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant; AND Patient must have a current height at or below the 1stpercentile for age and sex; OR Patient must have a current height above the 1stand at or below the 25thpercentiles for age and sex and a growth velocity less than or equal to the 25thpercentile 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 1stand at or below the 25thpercentiles 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 1stand at or below the 25thpercentiles 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 diabetes mellitus; 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 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 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. 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. 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 1stpercentile 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. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2; AND 6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; 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. | Compliance with Written Authority Required procedures |
| C8348 |  |  | Short stature and poor body composition due to Prader-Willi syndrome Initial treatment Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; OR Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; OR Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment; AND Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height; AND Patient must not have diabetes mellitus; 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 not have a chronological age of 18 years or greater. 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. 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 6 months of recent growth data (height, weight and waist circumference). The most recent data must not be older than three months; AND 4. The date at which skeletal maturity was achieved (if applicable) [Note: In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity]; AND 5. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome; OR (b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist 6. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months and any sleep disorders identified via polysomnography that required treatment have been addressed; 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 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. | Compliance with Written Authority Required procedures |
| C8349 |  |  | Biochemical growth hormone deficiency and precocious puberty Initial treatment Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR Patient must be female and menarche occurred before the chronological age of 10 years; 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 be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND Patient must not have diabetes mellitus; 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. 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. 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) at intervals no greater than six months. The most recent data must not be older than three months; OR (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). 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. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 6. Confirmation that the patient has precocious puberty; AND 7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND 8. 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. | Compliance with Written Authority Required procedures |
| C8357 |  |  | Growth retardation secondary to an intracranial lesion, or cranial irradiation 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 growth retardation secondary to an intracranial lesion, or cranial irradiation; 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 had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; 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 have had a height at or below the 1stpercentile for age and sex immediately prior to commencing treatment; OR Patient must have had both a height above the 1stpercentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25thpercentile 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 1stpercentile 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 1stpercentile 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 not have diabetes mellitus; 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. 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. 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 1stpercentile for age and sex immediately prior to commencing treatment; AND 4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND 6. 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 7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND 8. 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. 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. | Compliance with Written Authority Required procedures |
| C8358 |  |  | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven 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 hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven 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 a structural lesion that is not neoplastic; OR Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion; 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 have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies); AND Patient must have hypothalamic obesity; AND Patient must have had a growth velocity above the 25thpercentile 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 an annual growth velocity of greater than 14 cm per year 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 an annual growth velocity of greater than 8 cm per year 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 not have diabetes mellitus; 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. 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. 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 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); AND 4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND 6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND 7. Confirmation that the patient has hypothalamic obesity; AND 8. 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 9. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND 10. 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. | Compliance with Written Authority Required procedures |
| C8360 |  |  | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants Continuing treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants 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 diabetes mellitus; 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 a chronological age of 5 years or greater. 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. When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'. | Compliance with Written Authority Required procedures |
| C8361 |  |  | Biochemical growth hormone deficiency and precocious puberty Continuing treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty 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 diabetes mellitus; 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. 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. | Compliance with Written Authority Required procedures |
| C8362 |  |  | 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/1.73m2measured 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 1stpercentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25thpercentile 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); AND Patient must not have diabetes mellitus; 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. 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. 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; 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/1.73m2measured 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; 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. | Compliance with Written Authority Required procedures |
| C8365 |  |  | 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 1stpercentile for age and sex immediately prior to commencing treatment; OR Patient must have had both a height above the 1stand at or below the 25thpercentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25thpercentile 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 1stand at or below the 25thpercentiles 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 1stand at or below the 25thpercentiles 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 diabetes mellitus; 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. 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. 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 1stpercentile 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. | Compliance with Written Authority Required procedures |
| C8368 |  |  | Growth retardation secondary to an intracranial lesion, or cranial irradiation Continuing treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation 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 diabetes mellitus; 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. 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. | Compliance with Written Authority Required procedures |
| C8369 |  |  | Short stature associated with chronic renal insufficiency 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 chronic renal insufficiency; AND The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 had a height at or below the 1stpercentile for age and sex immediately prior to commencing treatment; OR Patient must have had both a height above the 1stand at or below the 25thpercentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25thpercentile 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 1stand at or below the 25thpercentiles 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 1stand at or below the 25thpercentiles 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 an estimated glomerular filtration rate less than 30mL/minute/1.73m2measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant; AND Patient must not have diabetes mellitus; 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 167.7cm; OR Patient must be female and must not have a height greater than or equal to 155.0cm; 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. 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. 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 1stpercentile for age and sex immediately prior to commencing treatment; AND 4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m2; AND 5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND 6. 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 7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND 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. | Compliance with Written Authority Required procedures |
| C8372 |  |  | 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 diabetes mellitus; 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. Patient must be aged 3 years or older. 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. | Compliance with Written Authority Required procedures |
| C8373 |  |  | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth Continuing treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven 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 diabetes mellitus; 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. Patient must be aged 3 years or older. 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. | Compliance with Written Authority Required procedures |
| C8376 |  |  | 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 diabetes mellitus; 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. 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. | Compliance with Written Authority Required procedures |
| C8377 |  |  | Short stature due to short stature homeobox (SHOX) gene disorders Continuing treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category; AND Patient must not have been on the maximum dose of 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 diabetes mellitus; AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); 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. 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. | Compliance with Written Authority Required procedures |
| C8378 |  |  | 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 diabetes mellitus; 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. Patient must be aged 3 years or older. 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. | Compliance with Written Authority Required procedures |
| C8380 |  |  | 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 diabetes mellitus; 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. 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. | Compliance with Written Authority Required procedures |
| C8386 |  |  | Biochemical growth hormone deficiency and precocious puberty Continuing treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty 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 diabetes mellitus; 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. Patient must be aged 3 years or older. 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. | Compliance with Written Authority Required procedures |
| C8388 |  |  | Short stature associated with chronic renal insufficiency Continuing treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category; AND Patient must not have been on the maximum dose of 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 diabetes mellitus; 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 undergone a renal transplant within the 12 month period immediately prior to the date of application; AND Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2; 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. Patient must be aged 3 years or older. 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. | Compliance with Written Authority Required procedures |
| C8389 |  |  | 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/1.73m2measured 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 1stpercentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25thpercentile 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); AND Patient must not have diabetes mellitus; 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 167.7 cm; OR Patient must be female and must not have a height greater than or equal to 155.0 cm. Patient must be aged 3 years or older. 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. 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; 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/1.73m2measured 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; 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. | Compliance with Written Authority Required procedures |
| C8393 |  |  | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth Continuing treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven 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 diabetes mellitus; 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. 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. | Compliance with Written Authority Required procedures |
| C8394 |  |  | Biochemical growth hormone deficiency and precocious puberty Continuing treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty; 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 be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR Patient must be female and menarche occurred before the chronological age of 10 years; 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 be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND Patient must not have diabetes mellitus; 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. 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. 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. Confirmation that the patient has precocious puberty; AND 4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND 5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 6. 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 7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND 8. 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. | Compliance with Written Authority Required procedures |
| C8396 |  |  | Short stature associated with chronic renal insufficiency Continuing treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category; AND Patient must not have been on the maximum dose of 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 diabetes mellitus; 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 undergone a renal transplant within the 12 month period immediately prior to the date of application; AND Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2; 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. Patient must be prepubertal. 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. | Compliance with Written Authority Required procedures |
| C8398 |  |  | Short stature associated with chronic renal insufficiency Continuing treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category; 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 been on the maximum dose of 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 diabetes mellitus; AND Patient must not have an active tumour or evidence of tumour growth or activity; AND Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application; AND Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2; 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. 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. | Compliance with Written Authority Required procedures |
| C8402 |  |  | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth Recommencement of treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven 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 diabetes mellitus; 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. 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. 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. | Compliance with Written Authority Required procedures |
| C8403 |  |  | Short stature due to short stature homeobox (SHOX) gene disorders 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 due to short stature homeobox (SHOX) gene disorders; 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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma; AND Patient must have had a height at or below the 1stpercentile for age and sex immediately prior to commencing treatment; AND Patient must have had a growth velocity below the 25thpercentile 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 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 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 not have diabetes mellitus; AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); 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 167.7cm; OR Patient must be female and must not have a height greater than or equal to 155.0cm; 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. 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. 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 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); AND 4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND 5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND 6. Recent growth data (height and weight, not older than three months); AND 7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND 8. 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. | Compliance with Written Authority Required procedures |
| C8407 |  |  | 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 1stpercentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25thpercentile 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); AND Patient must not have diabetes mellitus; 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. 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. 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; 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; 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. | Compliance with Written Authority Required procedures |
| C8411 |  |  | Short stature due to short stature homeobox (SHOX) gene disorders 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 due to short stature homeobox (SHOX) gene disorders; 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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma; AND Patient must have had a height at or below the 1stpercentile for age and sex immediately prior to commencing treatment; AND Patient must have had a growth velocity below the 25thpercentile 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 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 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 not have diabetes mellitus; AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); 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 167.7cm; OR Patient must be female and must not have a height greater than or equal to 155.0cm; 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. Patient must be aged 3 years or older. 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. 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 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); AND 4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND 5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND 6. Recent growth data (height and weight, not older than three months); AND 7. A bone age result performed within the last 12 months; AND 8. 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. | Compliance with Written Authority Required procedures |
| C8415 |  |  | 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 diabetes mellitus; 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. 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. 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. | Compliance with Written Authority Required procedures |
| C8416 |  |  | Biochemical growth hormone deficiency and precocious puberty Recommencement of treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty 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 be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND Patient must not have diabetes mellitus; 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. 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. 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. | Compliance with Written Authority Required procedures |
| C8417 |  |  | Growth retardation secondary to an intracranial lesion, or cranial irradiation 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 growth retardation secondary to an intracranial lesion, or cranial irradiation; 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 had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; 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 have had a height at or below the 1stpercentile for age and sex immediately prior to commencing treatment; OR Patient must have had both a height above 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 a height above the 1st percentile 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 percentile 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 not have diabetes mellitus; 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. 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. 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; AND 4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND 6. Recent growth data (height and weight, not older than three months); AND 7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND 8. 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. | Compliance with Written Authority Required procedures |
| C8418 |  |  | Biochemical growth hormone deficiency and precocious puberty Recommencement of treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty; 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 be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR Patient must be female and menarche occurred before the chronological age of 10 years; 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 be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND Patient must not have diabetes mellitus; 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. 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. 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. Confirmation that the patient has precocious puberty; AND 4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND 5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 6. Recent growth data (height and weight, not older than three months); AND 7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND 8. 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. | Compliance with Written Authority Required procedures |
| C8419 |  |  | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants Recommencement of treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants 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 diabetes mellitus; 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 a chronological age of 5 years or greater. 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. 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. | Compliance with Written Authority Required procedures |
| C8420 |  |  | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants Recommencement of treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants; 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 have a chronological age of less than 2 years; AND Patient must have a documented clinical risk of hypoglycaemia; AND Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND Patient must not have diabetes mellitus; 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. 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. 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. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND 4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND 5. Recent growth data (height and weight, not older than three months); 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. | Compliance with Written Authority Required procedures |
| C8422 |  |  | Growth retardation secondary to an intracranial lesion, or cranial irradiation Recommencement of treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation 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 diabetes mellitus; 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. 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. 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. | Compliance with Written Authority Required procedures |
| C8423 |  |  | Short stature associated with chronic renal insufficiency Recommencement of treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency 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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 diabetes mellitus; 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 undergone a renal transplant within the 12 month period immediately prior to the date of application; AND Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2; 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. 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. 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. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2; AND 6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; 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. If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2prescribers should seek reclassification to the indication short stature and slow growth. | Compliance with Written Authority Required procedures |
| C8424 |  |  | 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 1stpercentile for age and sex immediately prior to commencing treatment; OR Patient must have had both a height above the 1stand at or below the 25thpercentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25thpercentile 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 1stand at or below the 25thpercentiles 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 1stand at or below the 25thpercentiles 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 diabetes mellitus; 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. 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. 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. | Compliance with Written Authority Required procedures |
| C8425 |  |  | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven 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 hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven 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 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 structural lesion that is not neoplastic; OR Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies); AND Patient must have hypothalamic obesity; AND Patient must have had a growth velocity above the 25thpercentile 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 an annual growth velocity of greater than 14 cm per year 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 an annual growth velocity of greater than 8 cm per year 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 not have diabetes mellitus; 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. 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. 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 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); AND 4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND 6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND 7. Confirmation that the patient has hypothalamic obesity; AND 8. Recent growth data (height and weight, not older than three months); AND 9. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND 10. 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. | Compliance with Written Authority Required procedures |
| C8426 |  |  | Short stature due to short stature homeobox (SHOX) gene disorders Recommencement of treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders 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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma; AND Patient must not have diabetes mellitus; AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); 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. 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. 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. | Compliance with Written Authority Required procedures |
| C8427 |  |  | Short stature and poor body composition due to Prader-Willi syndrome Recommencement of treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and poor body composition due to Prader-Willi syndrome; 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 have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND Patient must have been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment and any sleep disorders identified that required treatment must have been addressed; OR Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; OR Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; OR Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment; AND Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height; AND Patient must not have diabetes mellitus; 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 a chronological age of 18 years or greater. 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. 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) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR (b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND 4. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment or within the last 12 months, and any sleep disorders identified via the polysomnography that required treatment have been addressed; AND 5. Recent growth data (height and weight, not older than three months); AND 6. The date at which skeletal maturity was achieved (if applicable) [Note: In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity]; 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. | Compliance with Written Authority Required procedures |
| C8429 |  |  | 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 1stpercentile for age and sex immediately prior to commencing treatment; OR Patient must have had both a height above the 1stand at or below the 25thpercentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25thpercentile 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 1stand at or below the 25thpercentiles 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 1stand at or below the 25thpercentiles 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 diabetes mellitus; 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. Patient must be aged 3 years or older. 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. 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. | Compliance with Authority Required procedures |
| C8433 |  |  | Short stature associated with chronic renal insufficiency 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 chronic renal insufficiency; 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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 had a height at or below the 1stpercentile for age and sex immediately prior to commencing treatment; OR Patient must have had both a height above the 1stand at or below the 25thpercentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25thpercentile 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 1stand at or below the 25thpercentiles 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 1stand at or below the 25thpercentiles 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 an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant; AND Patient must not have diabetes mellitus; 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 167.7cm; OR Patient must be female and must not have a height greater than or equal to 155.0cm; 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. 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. 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; AND 4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2; AND 5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND 6. Recent growth data (height and weight, not older than three months); AND 7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND 8. 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. | Compliance with Written Authority Required procedures |
| C8439 |  |  | Short stature associated with chronic renal insufficiency Recommencement of treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency 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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 diabetes mellitus; 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 undergone a renal transplant within the 12 month period immediately prior to the date of application; AND Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2; 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. 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. Patient must be prepubertal. 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. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2; AND 6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; 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. If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth. | Compliance with Written Authority Required procedures |
| C8449 |  |  | Short stature due to short stature homeobox (SHOX) gene disorders Initial treatment Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma; AND Patient must have a current height at or below the 1stpercentile for age and sex; AND Patient must have a growth velocity below the 25thpercentile 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 diabetes mellitus; AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); 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 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 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. Patient must be aged 3 years or older. 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. 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; AND 5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND 6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; 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. | Compliance with Written Authority Required procedures |
| C8452 |  |  | Short stature and poor body composition due to Prader-Willi syndrome Continuing treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and poor body composition due to Prader-Willi syndrome category; AND Patient must have been re-evaluated via polysomnography for airway obstruction and apnoea during the initial 32 week treatment period and any sleep disorders identified that required treatment must have been addressed; AND Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and 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 had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have maintained or improved height percentile for 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 had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have maintained or improved body mass index SDS for 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 had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have maintained or improved waist circumference 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 had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) 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 had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have achieved an increase in height percentile with reference to the untreated Prader-Willi syndrome standards for 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 had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must not have been on the maximum dose of 0.04mg/kg/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 had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved body mass index while on the maximum dose of 0.04mg/kg/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 had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved body mass index SDS for age and sex while on the maximum dose of 0.04mg/kg/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 had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved waist circumference while on the maximum dose of 0.04mg/kg/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 had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) while on the maximum dose of 0.04mg/kg/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 had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved weight SDS for age and sex while on the maximum dose of 0.04mg/kg/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 diabetes mellitus; 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 developed uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height. Patient must not have a chronological age of equal to or greater than 18 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; AND 3. Growth data (height, weight and waist circumference) 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. The date at which skeletal maturity was achieved (if applicable) [Note: In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity]; AND 5. Confirmation that during the initial 32 week treatment period, the patient was re-evaluated via polysomnography for airway obstruction and apnoea, and any sleep disorders that were identified have been addressed; 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. Maintenance is defined as a value within a 5% tolerance (this allows for seasonal and other measurement variations). | Compliance with Written Authority Required procedures |
| C8453 |  |  | Short stature and poor body composition due to Prader-Willi syndrome Continuing treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and poor body composition due to Prader-Willi syndrome; 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 diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND Patient must have been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment and any sleep disorders identified that required treatment must have been addressed; AND Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height; AND Patient must not have diabetes mellitus; 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 a chronological age of 18 years or greater. 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. 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) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR (b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND 4. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment, and any sleep disorders identified via the polysomnography that required treatment have been addressed; 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. The date at which skeletal maturity was achieved (if applicable) [Note: In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity]; 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. | Compliance with Written Authority Required procedures |
| C8456 |  |  | Short stature due to short stature homeobox (SHOX) gene disorders Continuing treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category; AND Patient must not have been on the maximum dose of 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 diabetes mellitus; AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); 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. Patient must be aged 3 years or older. 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. | Compliance with Written Authority Required procedures |
| C8457 |  |  | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven 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 hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven 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 a structural lesion that is not neoplastic; OR Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion; 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 have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies); AND Patient must have hypothalamic obesity; AND Patient must have had a growth velocity above the 25thpercentile 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 an annual growth velocity of greater than 14 cm per year 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 an annual growth velocity of greater than 8 cm per year 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 not have diabetes mellitus; 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. Patient must be aged 3 years or older. 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. 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 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); AND 4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND 6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND 7. Confirmation that the patient has hypothalamic obesity; AND 8. 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 9. A bone age result performed within the last 12 months; AND 10. 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. | Compliance with Written Authority Required procedures |
| C8459 |  |  | Growth retardation secondary to an intracranial lesion, or cranial irradiation 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 growth retardation secondary to an intracranial lesion, or cranial irradiation; 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 had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; 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 have had a height at or below the 1stpercentile for age and sex immediately prior to commencing treatment; OR Patient must have had both a height above the 1stpercentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25thpercentile 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 1stpercentile 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 1stpercentile 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 not have diabetes mellitus; 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. Patient must be aged 3 years or older. 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. 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 1stpercentile for age and sex immediately prior to commencing treatment; AND 4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND 6. 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 7. A bone age result performed within the last 12 months; AND 8. 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. | Compliance with Written Authority Required procedures |
| C8463 |  |  | 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 1stpercentile for age and sex immediately prior to commencing treatment; OR Patient must have had both a height above the 1stand at or below the 25thpercentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25thpercentile 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 1stand at or below the 25thpercentiles 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 1stand at or below the 25thpercentiles 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 diabetes mellitus; 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. Patient must be aged 3 years or older. 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. 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 1stpercentile 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. | Compliance with Written Authority Required procedures |
| C8464 |  |  | Biochemical growth hormone deficiency and precocious puberty Continuing treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty; 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 be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR Patient must be female and menarche occurred before the chronological age of 10 years; 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 be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND Patient must not have diabetes mellitus; 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. Patient must be aged 3 years or older. 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. 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. Confirmation that the patient has precocious puberty; AND 4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND 5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 6. 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 7. A bone age result performed within the last 12 months; AND 8. 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. | Compliance with Written Authority Required procedures |
| C8468 |  |  | Short stature and poor body composition due to Prader-Willi syndrome Recommencement of treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and poor body composition due to Prader Willi syndrome category; AND Patient must have had a lapse in growth hormone treatment; AND Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and 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 Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and 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 Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and 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 Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and 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 Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and 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; OR Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies); OR Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by a significant medical illness; OR Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by non-compliance due to social/family problems; AND Patient must have been re-evaluated via polysomnography for airway obstruction and apnoea during the initial 32 week treatment period and any sleep disorders identified that required treatment must have been addressed; AND Patient must not have diabetes mellitus; 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 developed uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height. Patient must not have a chronological age of equal to or greater than 18 years. 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. 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, weight, and waist circumference, not older than three months); AND 4. The date at which skeletal maturity was achieved (if applicable) [Note: In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity.]; AND 5. Confirmation that during the initial 32 week treatment period, the patient was re-evaluated via polysomnography for airway obstruction and apnoea, and any sleep disorders that were identified have been addressed; 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. | Compliance with Written Authority Required procedures |
| C8469 |  |  | 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 diabetes mellitus; 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. 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. Patient must be aged 3 years or older. 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. | Compliance with Written Authority Required procedures |
| C8471 |  |  | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven 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 hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven 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 a structural lesion that is not neoplastic; OR Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion; 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 have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies); AND Patient must have hypothalamic obesity; AND Patient must have had a growth velocity above the 25thpercentile 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 an annual growth velocity of greater than 14 cm per year 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 an annual growth velocity of greater than 8 cm per year 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 not have diabetes mellitus; 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. Patient must be aged 3 years or older. 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. 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 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); AND 4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND 6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND 7. Confirmation that the patient has hypothalamic obesity; AND 8. Recent growth data (height and weight, not older than three months); AND 9. A bone age result performed within the last 12 months; AND 10. 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. | Compliance with Authority Required procedures |
| C8472 |  |  | Short stature associated with chronic renal insufficiency 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 chronic renal insufficiency; 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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 had a height at or below the 1stpercentile for age and sex immediately prior to commencing treatment; OR Patient must have had both a height above the 1stand at or below the 25thpercentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25thpercentile 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 1stand at or below the 25thpercentiles 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 1stand at or below the 25thpercentiles 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 an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant; AND Patient must not have diabetes mellitus; 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 167.7cm; OR Patient must be female and must not have a height greater than or equal to 155.0cm; 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. Patient must be prepubertal. 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. 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; AND 4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2; AND 5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND 6. Recent growth data (height and weight, not older than three months); AND 7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND 8. 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. | Compliance with Written Authority Required procedures |
| C8480 |  |  | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth Initial treatment 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. Patient must have a structural lesion that is not neoplastic; OR Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion; 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 have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies); AND Patient must have hypothalamic obesity; AND Patient must have a growth velocity above the 25thpercentile 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 greater than 8 cm per year if the patient has a bone age of 2.5 years or less; AND Patient must not have diabetes mellitus; 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. Patient must be aged 3 years or older. 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; AND 5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND 7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND 8. Confirmation that the patient has hypothalamic obesity; AND 9. 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. Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced. | Compliance with Written Authority Required procedures |
| C8481 |  |  | Short stature and slow growth Initial treatment Patient must have a current height at or below the 1stpercentile for age and sex; AND Patient must have a growth velocity below the 25thpercentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); AND Patient must not have diabetes mellitus; 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 not have a bone age of 2.5 years or less; 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. Patient must be aged 3 years or older. 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. 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; 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 1stadult 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. | Compliance with Written Authority Required procedures |
| C8482 |  |  | Biochemical growth hormone deficiency and precocious puberty Initial treatment Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR Patient must be female and menarche occurred before the chronological age of 10 years; 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 be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND Patient must not have diabetes mellitus; 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. Patient must be aged 3 years or older. 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. 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) at intervals no greater than six months. The most recent data must not be older than three months; OR (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). 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. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 6. Confirmation that the patient has precocious puberty; AND 7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND 8. 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. | Compliance with Written Authority Required procedures |
| C8488 |  |  | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants Continuing treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants 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 diabetes mellitus; 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 a chronological age of 5 years or greater. Patient must be aged 3 years or older. 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. When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'. | Compliance with Written Authority Required procedures |
| C8489 |  |  | Growth retardation secondary to an intracranial lesion, or cranial irradiation Continuing treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation 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 diabetes mellitus; 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. Patient must be aged 3 years or older. 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. | Compliance with Written Authority Required procedures |
| C8490 |  |  | Short stature associated with chronic renal insufficiency 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 chronic renal insufficiency; AND The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 had a height at or below the 1stpercentile for age and sex immediately prior to commencing treatment; OR Patient must have had both a height above the 1stand at or below the 25thpercentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25thpercentile 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 1stand at or below the 25thpercentiles 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 1stand at or below the 25thpercentiles 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 an estimated glomerular filtration rate less than 30mL/minute/1.73m2measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant; AND Patient must not have diabetes mellitus; 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 167.7cm; OR Patient must be female and must not have a height greater than or equal to 155.0cm; 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. Patient must be aged 3 years or older. 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. 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 1stpercentile for age and sex immediately prior to commencing treatment; AND 4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m2; AND 5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND 6. 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 7. A bone age result performed within the last 12 months; AND 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. | Compliance with Written Authority Required procedures |
| C8492 |  |  | Growth retardation secondary to an intracranial lesion, or cranial irradiation 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 growth retardation secondary to an intracranial lesion, or cranial irradiation; 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 had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; 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 have had a height at or below the 1stpercentile for age and sex immediately prior to commencing treatment; OR Patient must have had both a height above 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 a height above the 1st percentile 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 percentile 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 not have diabetes mellitus; 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. Patient must be aged 3 years or older. 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. 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; AND 4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND 6. Recent growth data (height and weight, not older than three months); AND 7. A bone age result performed within the last 12 months; AND 8. 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. | Compliance with Written Authority Required procedures |
| C8494 |  |  | 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 1stpercentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25thpercentile 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); AND Patient must not have diabetes mellitus; 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. Patient must be aged 3 years or older. 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. 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; 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; 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. | Compliance with Written Authority Required procedures |
| C8495 |  |  | Biochemical growth hormone deficiency and precocious puberty Recommencement of treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty; 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 be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR Patient must be female and menarche occurred before the chronological age of 10 years; 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 be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND Patient must not have diabetes mellitus; 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. Patient must be aged 3 years or older. 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. 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. Confirmation that the patient has precocious puberty; AND 4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND 5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 6. Recent growth data (height and weight, not older than three months); AND 7. A bone age result performed within the last 12 months; AND 8. 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. | Compliance with Written Authority Required procedures |
| C8501 |  |  | Growth retardation secondary to an intracranial lesion, or cranial irradiation Initial treatment Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; 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 have a current height at or below the 1stpercentile for age and sex; OR Patient must have a current height above the 1stpercentile 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 1stpercentile 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 diabetes mellitus; 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. Patient must be aged 3 years or older. 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. 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. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; 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. | Compliance with Written Authority Required procedures |
| C8502 |  |  | Short stature associated with chronic renal insufficiency 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 chronic renal insufficiency; AND The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 had a height at or below the 1stpercentile for age and sex immediately prior to commencing treatment; OR Patient must have had both a height above the 1stand at or below the 25thpercentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25thpercentile 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 1stand at or below the 25thpercentiles 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 1stand at or below the 25thpercentiles 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 an estimated glomerular filtration rate less than 30mL/minute/1.73m2measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant; AND Patient must not have diabetes mellitus; 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 167.7cm; OR Patient must be female and must not have a height greater than or equal to 155.0cm; 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. Patient must be prepubertal. 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. 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 1stpercentile for age and sex immediately prior to commencing treatment; AND 4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m2; AND 5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND 6. 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 7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND 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. | Compliance with Written Authority Required procedures |
|  | C8503 |  |  | Short stature associated with chronic renal insufficiency 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 chronic renal insufficiency; 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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 had a height at or below the 1stpercentile for age and sex immediately prior to commencing treatment; OR Patient must have had both a height above the 1stand at or below the 25thpercentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25thpercentile 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 1stand at or below the 25thpercentiles 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 1stand at or below the 25thpercentiles 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 an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant; AND Patient must not have diabetes mellitus; 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 167.7cm; OR Patient must be female and must not have a height greater than or equal to 155.0cm; 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. Patient must be aged 3 years or older. 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. 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; AND 4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2; AND 5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND 6. Recent growth data (height and weight, not older than three months); AND 7. A bone age result performed within the last 12 months; AND 8. 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. | Compliance with Written Authority Required procedures |
|  | C8525 |  |  | Short stature associated with chronic renal insufficiency Initial treatment 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. Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant; AND Patient must have a current height at or below the 1stpercentile for age and sex; OR Patient must have a current height above the 1stand at or below the 25thpercentiles for age and sex and a growth velocity less than or equal to the 25thpercentile 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 1stand at or below the 25thpercentiles 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 diabetes mellitus; 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 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. Patient must be aged 3 years or older. 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 1stpercentile for age and sex; AND 4. A bone age result performed within the last 12 months; AND 5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2; AND 6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; 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. | Compliance with Written Authority Required procedures |
|  | C9221 |  |  | Short stature due to short stature homeobox (SHOX) gene disorders 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 due to short stature homeobox (SHOX) gene disorders; AND The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma; AND Patient must have had a height at or below the 1stpercentile for age and sex immediately prior to commencing treatment; AND Patient must have had a growth velocity below the 25thpercentile 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 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 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 not have diabetes mellitus; AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); 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 167.7cm; OR Patient must be female and must not have a height greater than or equal to 155.0cm; 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. 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. 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 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); AND 4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND 5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND 6. 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 7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND 8. 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. | Compliance with Written Authority Required procedures |
|  | C9257 |  |  | Short stature due to short stature homeobox (SHOX) gene disorders 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 due to short stature homeobox (SHOX) gene disorders; AND The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 9.5mg/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 diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma; AND Patient must have had a height at or below the 1stpercentile for age and sex immediately prior to commencing treatment; AND Patient must have had a growth velocity below the 25thpercentile 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 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 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 not have diabetes mellitus; AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); 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 167.7cm; OR Patient must be female and must not have a height greater than or equal to 155.0cm; 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. Patient must be aged 3 years or older. 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. 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 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); AND 4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND 5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND 6. 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 7. A bone age result performed within the last 12 months; AND 8. 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. | Compliance with Written Authority Required procedures |
|  | C10042 |  |  | Severe growth hormone deficiency Initial treatment of adult onset growth hormone deficiency Must be treated by an endocrinologist. Patient must have adult onset growth hormone deficiency secondary to organic hypothalamic or pituitary disease; AND Patient must have an insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; OR Patient must have an arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; OR Patient must have a glucagon provocation test with maximum serum GH less than 3 micrograms per litre. Patient must be aged 18 years or older. Grandfathered patient who has previously received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2018 must have met all the initial restriction criteria prior to initiating non-PBS subsidised treatment. Additional information of a baseline serum IGF-1 measurement, including the date of testing and laboratory reference range for age and sex, of less than 12 weeks prior to initiating non-PBS subsidised treatment with this drug for this condition must be provided at the time of application. A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. The authority application must be in writing and must include: A completed authority prescription form; AND A completed Severe Growth Hormone Deficiency supporting information form; AND Results of the growth hormone stimulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender; AND A baseline serum IGF-1 measurement, including the date of testing and laboratory reference range for age and sex, of less than 12 weeks old prior to initiating treatment. | Compliance with Written Authority Required procedures |
|  | C10113 |  |  | Severe growth hormone deficiency Initial treatment of childhood onset growth hormone deficiency in a patient who has received non-PBS subsidised treatment as a child Must be treated by an endocrinologist. Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause; AND Patient must have previously received non-PBS subsidised treatment with this drug for this condition as a child; AND Patient must have current or historical evidence of an insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; OR Patient must have current or historical evidence of an arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; OR Patient must have current or historical evidence of a glucagon provocation test with maximum serum GH less than 3 micrograms per litre. Patient must have a mature skeleton; OR Patient must have a diagnosis of Prader-Willi syndrome and be aged 18 years or older. The authority application must be in writing and must include: A completed authority prescription form; AND A completed Severe Growth Hormone Deficiency supporting information form; AND Results of the growth hormone stimulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender; AND A serum IGF-1 measurement, including the date of testing and laboratory reference range for age and sex, of less than 12 weeks old at the time of application. | Compliance with Written Authority Required procedures |
|  | C10132 |  |  | Severe growth hormone deficiency Continuing treatment in a person with a mature skeleton or aged 18 years or older Must be treated by an endocrinologist or in consultation with an endocrinologist. Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause in a patient with a mature skeleton, or, in a patient with Prader-Willi syndrome and aged 18 years or older; OR Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to adult onset growth hormone deficiency secondary to organic hypothalamic or pituitary disease in a patient aged 18 years or older; AND Patient must maintain IGF-1 levels within the normal range for age and sex. The authority application must be in writing and must include: A completed authority prescription form; AND A completed Severe Growth Hormone Deficiency supporting information form; AND A serum IGF-1 measurement, including the date of testing and laboratory reference range for age and sex, of less than 12 weeks old at the time of application. | Compliance with Written Authority Required procedures |
|  | C10133 |  |  | Severe growth hormone deficiency Initial treatment of childhood onset growth hormone deficiency in a patient who has received PBS-subsidised treatment as a child Must be treated by an endocrinologist. Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition as a child. Patient must have a mature skeleton; OR Patient must have a diagnosis of Prader-Willi syndrome and be aged 18 years or older. The authority application must be in writing and must include: A completed authority prescription form; AND A completed Severe Growth Hormone Deficiency supporting information form; AND A serum IGF-1 measurement, including the date of testing and laboratory reference range for age and sex, of less than 12 weeks old at the time of application. | Compliance with Written Authority Required procedures |
| Sonidegib | C7491 |  |  | Metastatic or locally advanced basal cell carcinoma Initial treatment or Continuing treatment – balance of supply Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| C7540 |  |  | Metastatic or locally advanced basal cell carcinoma 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 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 in writing and must include: a) A completed authority prescription form; and b) A completed Basal Cell Carcinoma Continuing PBS Authority Application Form - Supporting Information Form; and c) A confirmation statement from the treating doctor that the disease has not progressed; and d) In patients with locally advanced BCC, a letter from a surgically qualified clinician demonstrating that the condition remains inappropriate for surgery; or a letter from a radiation oncologist demonstrating 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. It is recommended that an application is submitted to the Department of Human Services 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. 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 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 | Compliance with Written Authority Required procedures |
| C7557 |  |  | Metastatic or locally advanced basal cell carcinoma 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 in writing and must include: a) A completed authority prescription form; and b) A completed Basal Cell Carcinoma Initial PBS Authority Application Form - Supporting Information Form; and c) A histological confirmation of BCC and whether the condition is metastatic or locally advanced; and d) A letter from a surgically qualified clinician demonstrating inappropriateness for surgery for patients with locally advanced BCC; and e) A letter from a radiation oncologist demonstrating inappropriateness for curative radiotherapy for patients with locally advanced BCC; and f) A signed patient acknowledgement. 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. It is recommended that an application is submitted to the Department of Human Services 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. 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 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. | Compliance with Written Authority Required procedures |
| Sorafenib | C7487 | P7487 |  | Stage IV clear cell variant renal cell carcinoma (RCC) Continuing treatment beyond 3 months Patient must have received an initial authority prescription for this drug for this condition; AND Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND The treatment must be the sole PBS-subsidised therapy for this condition. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 7487 |
|  | C8616 | P8616 |  | Advanced Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma  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 Child Pugh class A; AND Patient must not have received prior treatment with a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) for this condition; OR Patient must have developed intolerance to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal. | Compliance with Authority Required procedures - Streamlined Authority Code 8616 |
|  | C8617 | P8617 |  | Advanced Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma  Continuing treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop disease progression while receiving treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 8617 |
|  | C8621 | P8621 |  | Stage IV clear cell variant renal cell carcinoma (RCC)  Initial treatment Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor; AND Patient must have a WHO performance status of 2 or less; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures |
| Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate |  | P5613 |  | Constipation Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult. |  |
|  | P5640 |  | Constipation Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function. |  |
|  | P5685 |  | Anorectal congenital abnormalities |  |
|  | P5720 |  | Constipation Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility. |  |
|  | P5775 |  | Constipation Patient must be receiving palliative care. |  |
|  | P5776 |  | Terminal malignant neoplasia |  |
|  | P5804 |  | Megacolon |  |
|  | P6139 |  | Constipation Patient must be receiving palliative care. |  |
| Sotalol | C5664 |  |  | Severe cardiac arrhythmias |  |
| Soy lecithin | C6172 |  |  | Severe dry eye syndrome Patient must be sensitive to preservatives in multi-dose eye drops. | Compliance with Authority Required procedures - Streamlined Authority Code 6172 |
| Soy protein and fat formula with vitamins and minerals -- carbohydrate free | C6658 |  |  | Ketogenic diet Patient must have intractable seizures requiring treatment with a ketogenic diet; OR Patient must have a glucose transport protein defect; OR Patient must have pyruvate dehydrogenase deficiency; OR Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance. |  |
| Sterculia with frangula bark | C5613 | P5613 |  | Constipation Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult. |  |
| C5640 | P5640 |  | Constipation Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function. |  |
| P5685 | P5685 |  | Anorectal congenital abnormalities |  |
| C5720 | P5720 |  | Constipation Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility. |  |
| C5775 | P5775 |  | Constipation Patient must be receiving palliative care. |  |
| C5776 | P5776 |  | Terminal malignant neoplasia |  |
| C5804 | P5804 |  | Megacolon |  |
| C6139 | P6139 |  | Constipation Patient must be receiving palliative care. |  |
| Sucroferric oxyhydroxide | C5491 |  |  | Hyperphosphataemia Maintenance following initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease. | Compliance with Authority Required procedures - Streamlined Authority Code 5491 |
| C5530 |  |  | Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease. | Compliance with Authority Required procedures - Streamlined Authority Code 5530 |
|  | C9762 |  |  | Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease. | Compliance with Authority Required procedures - Streamlined Authority Code 9762 |
| Sulfasalazine |  | P4894 |  | For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |
| Sumatriptan | C5259 |  |  | Migraine attack The condition must have usually failed to respond to analgesics in the past. |  |
| Sunitinib | C4862 | P4862 |  | Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET) Initial treatment Patient must be symptomatic (despite somatostatin analogues); OR Patient must have disease progression; AND The treatment must be as monotherapy. Disease progression must be documented in the patient's medical records. Patients who have developed progressive disease on everolimus are not eligible to receive PBS-subsidised sunitinib for this condition. Patients who have developed intolerance to everolimus of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib. | Compliance with Authority Required procedures |
| C5249 | P5249 |  | Metastatic or unresectable malignant gastrointestinal stromal tumour Initial treatment The treatment must be as monotherapy; AND Patient must have a WHO performance status of 2 or less; AND Patient must have previously failed or be intolerant to imatinib mesylate. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Sunitinib Malate (Sutent) PBS Authority Application for Use in the Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form; and (3) a signed patient acknowledgement. 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 |
| C7430 | P7430 |  | Metastatic or unresectable malignant gastrointestinal stromal tumour Continuing treatment Patient must have received an initial authority prescription for this drug for this condition; AND The treatment must be as monotherapy; AND Patient must have a WHO performance status of 2 or less; AND Patient must not have progressive disease. | Compliance with Authority Required procedures - Streamlined Authority Code 7430 |
| C7466 | P7466 |  | Stage IV clear cell variant renal cell carcinoma (RCC) Continuing treatment beyond 3 months Patient must have received an initial authority prescription for this drug for this condition; AND Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib. | Compliance with Authority Required procedures - Streamlined Authority Code 7466 |
| C7471 | P7471 |  | Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET) Continuing treatment Patient must have received an initial authority prescription for this drug for this condition; AND Patient must not have disease progression; AND The treatment must be as monotherapy. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 7471 |
| C9210 | P9210 |  | Stage IV clear cell variant renal cell carcinoma (RCC) Initial treatment The condition must be classified as favourable to intermediate risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC); AND Patient must have a WHO performance status of 2 or less; AND The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition. Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib. | Compliance with Authority Required procedures - Streamlined Authority Code 9210 |
| Tacrolimus |  | P5569 | CN5569 | Management of rejection in patients following organ or tissue transplantation The treatment must be under the supervision and direction of a transplant unit; AND The treatment must include initiation, stabilisation, and review of therapy as required. | Compliance with Authority Required procedures - Streamlined Authority Code 5569 |
|  |  | P9697 | CN9697 | Management of rejection in patients following organ or tissue transplantation The treatment must be under the supervision and direction of a transplant unit; AND The treatment must include initiation, stabilisation, and review of therapy as required. | Compliance with Authority Required procedures - Streamlined Authority Code 9697 |
| Tamoxifen | C6381 | P6381 |  | Breast cancer The condition must be hormone receptor positive. |  |
| C6421 | P6421 |  | Reduction of breast cancer risk Patient must have a moderate or high risk of developing breast cancer; AND The treatment must not exceed a dose of 20 mg per day; AND The treatment must not exceed a lifetime maximum of 5 years for this condition. |  |
| C6449 | P6449 |  | Breast cancer The condition must be hormone receptor positive. |  |
| C6470 |  |  | Breast cancer The condition must be hormone receptor positive. |  |
| Tapentadol | C10445 |  |  | Chronic severe pain The condition must require daily, continuous, long term therapy with this treatment; AND Patient must have pain directly attributable to cancer; OR Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid or other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid or other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid or other opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management has been reviewed through consultation with the patient by another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed immediately prior to the first application or at least once in the past 12 months for subsequent applications. The full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management has not been reviewed through consultation with the patient by another medical practitioner to confirm the clinical need for continuing opioid analgesic treatment. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner consulted and the date of the consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats). | Compliance with Authority Required procedures - Streamlined Authority Code 10445 |
| Telmisartan with amlodipine | C4373 |  |  | Hypertension The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an angiotensin II antagonist; OR The condition must be inadequately controlled with a dihydropyridine calcium channel blocker. |  |
| Telmisartan with hydrochlorothiazide | C4374 |  |  | Hypertension The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an angiotensin II antagonist; OR The condition must be inadequately controlled with a thiazide diuretic. |  |
| Temazepam |  | P5661 | CN5661 | Malignant neoplasia (late stage) | Compliance with Authority Required procedures |
|  | P5941 | CN5941 | Insomnia Patient must be receiving this drug for the management of insomnia; AND Patient must be receiving long-term nursing care; AND Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult; AND Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal. | Compliance with Authority Required procedures |
|  | P5950 | CN5950 | Insomnia Patient must be receiving this drug for the management of insomnia; AND Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility; AND Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal. | Compliance with Authority Required procedures |
|  | P6175 | CN6175 | Insomnia Patient must be receiving palliative care. | Compliance with Authority Required procedures |
| Temozolomide |  | P4897 |  | Glioblastoma multiforme Patient must be undergoing concomitant radiotherapy. |  |
| Tenecteplase | C5783 |  |  | Acute myocardial infarction The treatment must be administrated within 12 hours of onset of attack. |  |
| Tenofovir | C6980 | P6980 |  | Chronic hepatitis B infection Patient must have cirrhosis; AND Patient must be nucleoside analogue naive; AND Patient must have detectable HBV DNA; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 6980 |
| C6982 | P6982 |  | HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 6982 |
| C6983 | P6983 |  | Chronic hepatitis B infection Patient must have cirrhosis; AND Patient must have failed antihepadnaviral therapy; AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 6983 |
| C6984 | P6984 |  | Chronic hepatitis B infection Patient must not have cirrhosis; AND Patient must have failed antihepadnaviral therapy; AND Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance. | Compliance with Authority Required procedures - Streamlined Authority Code 6984 |
| C6992 | P6992 |  | Chronic hepatitis B infection Patient must not have cirrhosis; AND Patient must be nucleoside analogue naive; AND Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection; AND Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy; AND The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 6992 |
| C6998 | P6998 |  | HIV infection Initial Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 6998 |
|  | C10362 | P10362 |  | Chronic hepatitis B infection Patient must be in the third trimester of pregnancy; AND Patient must have elevated HBV DNA levels greater than 200,000 IU/mL (1,000,000 copies/mL), in conjunction with documented hepatitis B infection. | Compliance with Authority Required procedures - Streamlined Authority Code 10362 |
| Tenofovir alafenamide with emtricitabine, elvitegravir and cobicistat | C4470 |  |  | HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection. | Compliance with Authority Required procedures - Streamlined Authority Code 4470 |
| C4522 |  |  | HIV infection Initial Patient must be antiretroviral treatment naive. | Compliance with Authority Required procedures - Streamlined Authority Code 4522 |
| Tenofovir with emtricitabine | C6985 |  |  | HIV infection Initial Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 6985 |
| C6986 |  |  | HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 6986 |
| C7580 |  |  | Pre-exposure prophylaxis (PrEP) against human immunodeficiency virus (HIV) infection The treatment must be for patients at medium to high risk of HIV infection, as defined by the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) Guidelines; AND Patient must have a negative HIV test result prior to treatment with PBS-subsidised therapy with this drug. Patient must be 18 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 7580 |
| Tenofovir with emtricitabine and efavirenz | C4470 |  |  | HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection. | Compliance with Authority Required procedures - Streamlined Authority Code 4470 |
| C4522 |  |  | HIV infection Initial Patient must be antiretroviral treatment naive. | Compliance with Authority Required procedures - Streamlined Authority Code 4522 |
| Terbinafine | C6395 | P6395 |  | Onychomycosis The condition must be proximal or extensive (greater than 80% nail involvement); AND Patient must have failed to respond to topical treatment; AND The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider; OR The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider. The date of the pathology report must be provided at the time of application and must not be more than 12 months old | Compliance with Authority Required procedures |
| C6404 | P6404 |  | Dermatophyte infection Patient must have failed to respond to topical treatment. Patient must be an Aboriginal or a Torres Strait Islander person. | Compliance with Authority Required procedures |
| C6412 |  |  | Fungal or yeast infection The condition must be fungal; OR The condition must be due to yeast. Patient must be 18 years of age or less. | Compliance with Authority Required procedures - Streamlined Authority Code 6412 |
| C6434 |  |  | Fungal or yeast infection Patient must be an Aboriginal or a Torres Strait Islander person. | Compliance with Authority Required procedures - Streamlined Authority Code 6434 |
| C6453 | P6453 |  | Dermatophyte infection Patient must have failed to respond to topical treatment; AND Patient must have failed to respond to griseofulvin. Patient must be 18 years of age or less. | Compliance with Authority Required procedures |
| Terbutaline | C9828 |  |  | Bronchospasm Patient must be unable to achieve co-ordinated use of a metered dose inhaler containing a short-acting beta-2 agonist; OR Patient must have developed a clinically important product-related adverse event during treatment with another short-acting beta-2 agonist. Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine. | Compliance with Authority Required procedures - Streamlined Authority Code 9828 |
| Teriflunomide | C10150 |  |  | 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 a 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 10150 |
|  | C10199 |  |  | 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 a 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 10199 |
| Teriparatide | C4113 |  |  | Severe established osteoporosis Continuing treatment Patient must have previously been issued with an authority prescription for this drug; AND The treatment must not exceed a lifetime maximum of 18 months therapy. | Compliance with Authority Required procedures |
| C6305 |  |  | Severe established osteoporosis Initial treatment Must be treated by a specialist; OR Must be treated by a consultant physician. Patient must be at very high risk of fracture; AND Patient must have a bone mineral density (BMD) T-score of -3.0 or less; AND Patient must have had 2 or more fractures due to minimal trauma; AND Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses; AND The treatment must be the sole PBS-subsidised agent; AND The treatment must not exceed a lifetime maximum of 18 months therapy. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated. If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated. Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum. Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application. | Compliance with Authority Required procedures |
| Testosterone | C6324 |  |  | Androgen deficiency Patient must not have an established pituitary or testicular disorder; AND The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs. Patient must be aged 40 years or older. Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. Androgen deficiency is defined as: (i) testosterone level of less than 6 nmol per litre; OR (ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher). Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings. The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated. The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |
| C6910 |  |  | Androgen deficiency Patient must have an established pituitary or testicular disorder. Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |
| C6919 |  |  | Pubertal induction Patient must be under 18 years of age. Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |
| C6933 |  |  | Micropenis Patient must be under 18 years of age. Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |
| C6934 |  |  | Constitutional delay of growth or puberty Patient must be under 18 years of age. Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |
| Tetrabenazine | C5340 |  |  | Hyperkinetic extrapyramidal disorders | Compliance with Authority Required procedures - Streamlined Authority Code 5340 |
| Tetracosactide | C7484 |  |  | Hypsarrhythmia and/or infantile spasms |  |
| Thalidomide | C5914 |  |  | Multiple myeloma | Compliance with Authority Required procedures - Streamlined Authority Code 5914 |
| C9290 |  |  | Multiple myeloma | Compliance with Authority Required procedures - Streamlined Authority Code 9290 |
| Thiamine | C5139 |  |  | Thiamine deficiency The treatment must be for prophylaxis. Patient must be an Aboriginal or a Torres Strait Islander person. | Compliance with Authority Required procedures - Streamlined Authority Code 5139 |
| Thyrotropin alfa | C5296 |  |  | Ablation of thyroid remnant tissue Patient must have undergone a thyroidectomy; AND The treatment must be in combination with radioactive iodine; AND Patient must not have a known metastatic disease. |  |
| Tiagabine | C4928 |  |  | Partial epileptic seizures The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs. | Compliance with Authority Required procedures - Streamlined Authority Code 4928 |
| Ticagrelor | C5746 |  |  | Acute coronary syndrome (myocardial infarction or unstable angina) The treatment must be in combination with aspirin. | Compliance with Authority Required procedures - Streamlined Authority Code 5746 |
| Tildrakizumab | C8475 | P8475 |  | Severe chronic plaque psoriasis Continuing treatment, Whole body or Continuing treatment, Face, hand, foot or Grandfathered patients - balance of supply Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Grandfathered treatment, Whole body restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Grandfathered treatment, Face, hand, foot restriction to complete 24 weeks treatment; AND The treatment must be as systemic monotherapy (other than methotrexate); AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. Must be treated by a dermatologist. | Compliance with Written Authority Required procedures |
|  | C8872 | P8872 |  | 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 28 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 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 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 |
|  | C8908 | P8908 |  | Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 1 month old at the time of application. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to 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. At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter. | Compliance with Written Authority Required procedures |
|  | C8933 | P8933 |  | Severe chronic plaque psoriasis Initial treatment - Face, hand, foot, Grandfathered patients Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND Patient must have received non-PBS subsidised therapy with this drug for this condition prior to 1 February 2019; AND Patient must have had disease, prior to treatment with this drug for this condition, classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling were rated as severe or very severe; or (ii) the skin area affected was 30% or more of the face, palm of a hand or sole of a foot; AND Patient must have demonstrated an adequate response following at least 12 weeks of non-PBS-subsidised treatment with this drug for this condition; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The PASI assessment must be performed on the same affected area as assessed at baseline or prior to initiation of treatment with this drug. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug) and the most recent PASI assessment. The most recent PASI assessment must be no more than 1 month old at the time of application. A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. | Compliance with Written Authority Required procedures |
|  | C8953 | P8953 |  | Severe chronic plaque psoriasis Continuing treatment, Whole body Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C8970 | P8970 |  | Severe chronic plaque psoriasis Initial treatment - Whole body, Grandfathered patients Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must have received non-PBS subsidised therapy with this drug for this condition prior to 1 February 2019; AND Patient must have had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with this drug for this condition; AND Patient must have demonstrated a response to treatment as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with this drug for this condition (whole body); AND Patient must have demonstrated an adequate response following at least 12 weeks of non-PBS-subsidised treatment with this drug for this condition; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheets including the date of the assessment of the patient's condition at baseline (prior to initiation of non-PBS subsidised therapy with this drug) and the most recent PASI assessment; and (ii) the completed PASI calculation sheet demonstrating response. The most recent PASI assessment must be no more than 1 month old at the time of application. A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. | Compliance with Written Authority Required procedures |
|  | C8972 | P8972 |  | Severe chronic plaque psoriasis Initial treatment - Initial 1, Face, hand, foot (new patient) Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 1 month old at the time of application. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to 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 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. At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter. | Compliance with Written Authority Required procedures |
|  | C8994 | P8994 |  | Severe chronic plaque psoriasis Continuing treatment, Face, hand, foot Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C8995 | P8995 |  | 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 28 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 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 |
|  | C8996 | P8996 |  | Severe chronic plaque psoriasis Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years ) restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; AND The treatment must be as systemic monotherapy (other than methotrexate); AND The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions. Must be treated by a dermatologist. | Compliance with Authority Required procedures |
|  | C9947 | P9947 |  | 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 28 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or 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. At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter. | Compliance with Written Authority Required procedures |
|  | C9997 | P9997 |  | 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 28 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or 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; 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. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter. | Compliance with Written Authority Required procedures |
| Tiotropium | C5509 |  |  | Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease Long-term maintenance treatment |  |
| C6352 |  |  | Chronic obstructive pulmonary disease (COPD) |  |
| C8605 |  |  | Severe asthma  Patient must have experienced at least one severe exacerbation, which has required documented use of systemic corticosteroids, in the previous 12 months while receiving optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented; AND The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated. Patient must be aged 18 years or older. Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist. |  |
| C8606 |  |  | Severe asthma  Must be treated by a respiratory physician, paediatric respiratory physician, clinical immunologist, allergist, paediatrician or general physician experienced in the management of patients with severe asthma; or in consultation with one of these specialists. Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented; AND Patient must have experienced at least one severe exacerbation prior to receiving PBS-subsidised treatment with this drug for this condition, which has required documented use of systemic corticosteroids in the previous 12 months while receiving optimised asthma therapy; OR Patient must have experienced frequent episodes of moderate asthma exacerbations prior to receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated. Patient must be aged 6 to 17 years inclusive. Optimised asthma therapy includes adherence to the maintenance combination of a medium to high dose ICS and a LABA. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative | Compliance with Authority Required procedures - Streamlined Authority Code 8606 |
| Tiotropium with olodaterol | C7798 |  |  | Chronic obstructive pulmonary disease (COPD)  Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR  Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR  Patient must have been stabilised on a combination of a LAMA and a LABA. | Compliance with Authority Required procedures - Streamlined Authority Code 7798 |
| Tipranavir | C5764 |  |  | HIV infection The treatment must be in addition to optimised background therapy; AND The treatment must be in combination with other antiretroviral agents; AND Patient must be antiretroviral experienced; AND The treatment must be co-administered with 200 mg ritonavir twice daily; AND Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity. | Compliance with Authority Required procedures - Streamlined Authority Code 5764 |
| Tirofiban | C5691 |  |  | Non-Q-wave myocardial infarction | Compliance with Authority Required procedures - Streamlined Authority Code 5691 |
| C5782 |  |  | High risk of unstable angina Patient must have new transient or persistent ST-T ischaemic changes; AND Patient must have pain lasting longer than 20 minutes. | Compliance with Authority Required procedures - Streamlined Authority Code 5782 |
| C5809 |  |  | High risk of unstable angina Patient must have new transient or persistent ST-T ischaemic changes; AND Patient must have repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours. | Compliance with Authority Required procedures - Streamlined Authority Code 5809 |
| Tobramycin | C4456 | P4456 |  | Proven Pseudomonas aeruginosa infection Initial treatment Patient must have cystic fibrosis; AND Patient must have been assessed for bronchial hyperresponsiveness as per the TGA-approved Product Information, with a negative test result; AND Patient must be participating in a four week trial of tobramycin inhalation powder and will be assessed for ability to tolerate the dry powder formulation in order to qualify for continued PBS-subsidised therapy. The trial commencement date must be documented in the patient's medical records. Patient must be 6 years of age or older. | Compliance with Authority Required procedures - Streamlined Authority Code 4456 |
| C4513 | P4513 |  | Proven Pseudomonas aeruginosa infection Continuing treatment Patient must have cystic fibrosis; AND Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules; AND Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s). Patient must be 6 years of age or older. | Compliance with Authority Required procedures - Streamlined Authority Code 4513 |
| C5446 |  |  | Septicaemia, suspected |  |
| C5451 |  |  | Perioperative use in ophthalmic surgery |  |
| C5476 |  |  | Perioperative use in ophthalmic surgery |  |
| C5477 |  |  | Suspected Pseudomonal eye infection |  |
| C5483 |  |  | Invasive ocular infection |  |
| C5490 |  |  | Septicaemia, proven |  |
| C5498 |  |  | Pseudomonas aeruginosa infection Patient must have cystic fibrosis; AND The treatment must be systemic. |  |
| C5499 |  |  | Suspected Pseudomonal eye infection |  |
| C5519 |  |  | Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent |  |
| C5520 |  |  | Proven Pseudomonas aeruginosa infection Patient must have cystic fibrosis; AND The treatment must be for management. | Compliance with Authority Required procedures - Streamlined Authority Code 5520 |
| Tocilizumab | C8627 | P8627 |  | Severe active rheumatoid arthritis  Continuing Treatment - balance of supply. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |
| C8631 | P8631 |  | Severe active rheumatoid arthritis Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. 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 Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. 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. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
| C8633 | P8633 |  | Severe active rheumatoid arthritis Continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response 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 Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
|  | C8638 | P8638 |  | Severe active rheumatoid arthritis  Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
|  | C8739 | P8739 |  | Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with 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 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response 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) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 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 Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. 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. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
|  | C8740 | P8740 |  | Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or 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 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. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. | Compliance with Written Authority Required procedures |
|  | C9148 | P9148 |  | Active giant cell arteritis Initial treatment Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis. Patient must have clinical symptoms of active giant cell arteritis in the absence of any other identifiable cause; AND Patient must have an ESR equal to or greater than 30 mm/hour within the past 6 weeks; OR Patient must have a CRP equal to or greater than 10 mg/L within the past 6 weeks; OR Patient must have active giant cell arteritis confirmed by positive temporal artery biopsy or imaging; AND Patient must have had a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis; AND Patient must have had temporal artery biopsy revealing features of giant cell arteritis at diagnosis; OR Patient must have had evidence of large-vessel vasculitis by magnetic resonance (MR) or computed tomography (CT) angiography or PET/CT at diagnosis; AND The treatment must be in combination with a tapering course of corticosteroids; AND The treatment must not exceed 52 weeks in total including initial and continuing applications. Patient must be aged 50 years or older. Clinical symptoms of giant cell arteritis at diagnosis include unequivocal cranial symptoms of giant cell arteritis (new onset localized headache, scalp tenderness, temporal artery tenderness or decreased pulsation, ischemia related vision loss, or otherwise unexplained mouth or jaw pain upon mastication); or symptoms of polymyalgia rheumatica, defined as shoulder and/or hip girdle pain associated with inflammatory morning stiffness. The authority application must be made in writing and must include: (1) a completed authority prescription form; (2) a completed Giant Cell Arteritis - Supporting Information Form; and (3) documentation that the patient has active giant cell arteritis including pathology reports outlining the patient's ESR or CRP levels within the last 6 weeks, or positive temporal artery biopsy or imaging; (4) documentation that the patient has been diagnosed with giant cell arteritis with a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis. | Compliance with Written Authority Required procedures |
|  | C9180 | P9180 |  | Active giant cell arteritis Continuing treatment Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed 52 weeks in total including initial and continuing applications. | Compliance with Authority Required procedures |
|  | C9380 | P9380 |  | Severe active juvenile idiopathic arthritis Continuing Treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |
|  | C9382 | P9382 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints. Patient must be under 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 measures of joint count must be no more than 4 weeks old at the time of this application. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints. Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C9383 | P9383 |  | Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must be under 30kg; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
|  | C9384 | P9384 |  | Severe active juvenile idiopathic arthritis Continuing treatment - balance of supply Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |
|  | C9386 | P9386 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
|  | C9390 | P9390 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C9391 | P9391 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Active joints are defined as: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count must be no more than 4 weeks old at the time of this application. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C9474 | P9474 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle. Patient must be under 18 years of age. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
|  | C9477 | P9477 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 16 or 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 or 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 or 24 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions for patients 30 kg or over; OR The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions for patients under 30 kg. | Compliance with Authority Required procedures |
|  | C9478 | P9478 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
|  | C9520 | P9520 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months. Patient must be under 18 years of age. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: (a) an active joint count of at least 20 active (swollen and tender) joints; OR (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction. An 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 |
|  | C9553 | P9553 |  | Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
|  | C9609 | P9609 |  | Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must be 30kg or over; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| Tofacitinib | C8627 | P8627 |  | Severe active rheumatoid arthritis  Continuing Treatment - balance of supply. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |
| C8631 | P8631 |  | Severe active rheumatoid arthritis Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. 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 Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. 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. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
| C8638 | P8638 |  | Severe active rheumatoid arthritis  Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
|  | C8725 | P8725 |  | Severe active rheumatoid arthritis Continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response 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 Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
|  | C8726 | P8726 |  | Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with 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 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response 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) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 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 Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. 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. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
|  | C8750 | P8750 |  | Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or 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 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. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. | Compliance with Written Authority Required procedures |
|  | C9064 | P9064 |  | Severe psoriatic arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. | Compliance with Authority Required procedures |
|  | C9069 | P9069 |  | Severe psoriatic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C9116 | P9116 |  | Severe psoriatic arthritis Continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C9141 | P9141 |  | Severe psoriatic arthritis Continuing treatment or Grandfathered patients - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received insufficient therapy with this drug for this condition under the Continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Grandfathered treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |
|  | C9155 | P9155 |  | Severe psoriatic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. 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 |
|  | C9157 | P9157 |  | Severe psoriatic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C9170 | P9170 |  | Severe psoriatic arthritis Initial treatment - Grandfather treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 May 2019; AND Patient must be receiving treatment with this drug for this condition at the time of application; 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 prior to initiating non-PBS subsidised treatment with this drug for this condition; 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 prior to initiating non-PBS subsidised treatment with this drug for this condition; 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 prior to initiating non-PBS subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response following at least 12 weeks of non-PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. 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. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The assessment of the patient's response to this PBS-subsidised course of therapy must be conducted no later than 4 weeks from the cessation of the treatment course. 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. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and (3) the date of commencement of this drug; and (4) results of the baseline patient assessment prior to initiation of non-PBS subsidised therapy with this drug. | Compliance with Written Authority Required procedures |
| Tolvaptan | C8288 |  |  | Autosomal dominant polycystic kidney disease (ADPKD)  Continuing treatment  Must be treated by a nephrologist or in consultation with a nephrologist.  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have end-stage renal disease defined as an estimated glomerular filtration rate (eGFR) of less than 15 mL/min/1.73m2; AND Patient must not have had a kidney transplant. | Compliance with Authority Required procedures - Streamlined Authority Code 8288 |
|  | C10250 |  |  | Autosomal dominant polycystic kidney disease (ADPKD) Initial treatment Must be treated by a nephrologist. Patient must have an estimated glomerular filtration rate (eGFR) between 30 and 89 mL/min 1.73 m2at the initiation of treatment with this drug for this condition; AND Patient must have or have had rapidly progressing disease at the time of initiation of this drug for this condition. Rapidly progressing disease is defined as either of the following: A decline in eGFR of greater than or equal to 5 mL/min/1.73 m2within one year; OR An average decline in eGFR of greater than or equal to 2.5 mL/min/1.73 m2per year over a five year period. | Compliance with Authority Required procedures |
| Topiramate | C5173 |  |  | Seizures Patient must have partial epileptic seizures; OR Patient must have primary generalised tonic-clonic seizures; OR Patient must have seizures of the Lennox-Gastaut syndrome; AND The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; AND Patient must be unable to take a solid dose form of topiramate. | Compliance with Authority Required procedures - Streamlined Authority Code 5173 |
| C5325 |  |  | Migraine The treatment must be for prophylaxis; AND Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months; AND Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker; AND Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen. Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 5325 |
| C5516 |  |  | Seizures Patient must have partial epileptic seizures; OR Patient must have primary generalised tonic-clonic seizures; OR Patient must have seizures of the Lennox-Gastaut syndrome; AND The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs. | Compliance with Authority Required procedures - Streamlined Authority Code 5516 |
| Topotecan | C6238 |  |  | Advanced metastatic ovarian cancer Patient must have failed prior therapy which included a platinum compound. | Compliance with Authority Required procedures - Streamlined Authority Code 6238 |
| Tramadol | C10442 | P10442 |  | Severe pain The treatment must be for short term therapy of acute severe pain; AND Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of other non-opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use other non-opioid analgesics due to contraindications, adverse effects or intolerance. |  |
|  | C10444 | P10444 |  | Severe pain Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of other non-opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use other non-opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management and clinical need for continuing opioid treatment has been reviewed and confirmed through consultation with the patient by another medical practitioner. The review must have been in the past 12 months and the full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iv) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management and need for continuing opioid treatment has not been reviewed through consultation with the patient by another medical practitioner. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner and the date of the planned consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats). |  |
|  | C10445 |  |  | Chronic severe pain The condition must require daily, continuous, long term therapy with this treatment; AND Patient must have pain directly attributable to cancer; OR Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid or other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid or other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid or other opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management has been reviewed through consultation with the patient by another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed immediately prior to the first application or at least once in the past 12 months for subsequent applications. The full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management has not been reviewed through consultation with the patient by another medical practitioner to confirm the clinical need for continuing opioid analgesic treatment. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner consulted and the date of the consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats). | Compliance with Authority Required procedures - Streamlined Authority Code 10445 |
|  | C10446 | P10446 |  | Severe pain Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of other non-opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use other non-opioid analgesics due to contraindications, adverse effects or intolerance. |  |
| Trametinib | C6752 | P6752 |  | Unresectable Stage III or Stage IV malignant melanoma Continuing treatment Patient must have previously been issued with an authority prescription for this drug; AND Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition; AND Patient must have stable or responding disease. | Compliance with Authority Required procedures - Streamlined Authority Code 6752 |
|  | C10051 | P10051 |  | Unresectable Stage III or Stage IV malignant melanoma Initial treatment Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10051 |
|  | C10130 | P10130 |  | Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma Continuing treatment Patient must have previously been issued with an authority prescription for trametinib and dabrafenib concomitantly for adjuvant treatment following complete surgical resection; AND Patient must not have experienced disease recurrence; AND Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. | Compliance with Authority Required procedures |
|  | C10131 | P10131 |  | Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma Grandfather treatment Patient must have previously received non-PBS subsidised drug for adjuvant treatment following complete surgical resection prior to 1 November 2019; AND The condition must be positive for a BRAF V600 mutation; AND Patient must have a WHO performance status of 1 or less prior to starting non-PBS treatment with this drug; AND Patient must not have evidence of recurrence; AND Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition; AND Patient must not have received prior PBS-subsidised treatment for this condition; AND Patient must have commenced non-PBS-subsidised treatment within 12 weeks of complete surgical resection; AND Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. | Compliance with Authority Required procedures |
|  | C10148 | P10148 |  | Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma Initial treatment The treatment must be adjuvant to complete surgical resection; AND The condition must be positive for a BRAF V600 mutation; AND Patient must have a WHO performance status of 1 or less; AND Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition; AND Patient must not have received prior PBS-subsidised treatment for this condition; AND The treatment must commence within 12 weeks of complete resection; AND Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. | Compliance with Authority Required procedures |
| Trandolapril with verapamil | C4390 |  |  | Hypertension The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an ACE inhibitor; OR The condition must be inadequately controlled with verapamil. |  |
| Trastuzumab | C9349 |  |  | Metastatic (Stage IV) HER2 positive breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug 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. Where a patient has a break in trastuzumab therapy of more than 1 week from when the last dose was due, a new loading dose may be required. | Compliance with Authority Required procedures - Streamlined Authority Code 9349 |
|  | C9353 | P9353 |  | 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; 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. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 9353 |
|  | C9462 | P9462 |  | Metastatic (Stage IV) HER2 positive breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug 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. | Compliance with Authority Required procedures - Streamlined Authority Code 9462 |
|  | C9571 |  |  | Metastatic (Stage IV) HER2 positive adenocarcinoma of the stomach or gastro-oesophageal junction Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease; 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. | Compliance with Authority Required procedures - Streamlined Authority Code 9571 |
|  | C9573 |  |  | Metastatic (Stage IV) HER2 positive adenocarcinoma of the stomach or gastro-oesophageal junction Initial treatment Patient must have evidence of human epidermal growth factor receptor 2 (HER2) positivity as demonstrated by immunohistochemistry 2+ or more in tumour material; AND Patient must have evidence of HER2 gene amplification as demonstrated by in situ hybridisation results based on more than 6 copies of HER2 in the same tumour tissue sample; AND Patient must have evidence of HER2 gene amplification as demonstrated by in situ hybridisation results based on the ratio of HER2 to chromosome 17 being more than 2 in the same tumour tissue sample; AND Patient must commence treatment in combination with platinum based chemotherapy and capecitabine; OR Patient must commence treatment in combination with platinum based chemotherapy and 5 fluorouracil; AND Patient must not have previously received this drug for this condition; AND Patient must not have received prior chemotherapy for this condition; AND Patient must have a WHO performance status of 2 or less; 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. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 9573 |
|  | C10212 | P10212 |  | Early HER2 positive breast cancer 3 weekly treatment regimen Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant); 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; AND Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10212 |
|  | C10213 |  |  | Early HER2 positive breast cancer Continuing treatment (weekly regimen) Patient must have previously received PBS-subsidised treatment with this drug 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; AND Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance. | Compliance with Authority Required procedures - Streamlined Authority Code 10213 |
|  | C10293 |  |  | Early HER2 positive breast cancer Initial treatment (3 weekly regimen) Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant); 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; AND Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance. HER2 positivity must be demonstrated by in situ hybridisation (ISH). Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10293 |
|  | C10294 |  |  | Early HER2 positive breast cancer Continuing treatment (3 weekly regimen) Patient must have previously received PBS-subsidised treatment with this drug 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; AND Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance. | Compliance with Authority Required procedures - Streamlined Authority Code 10294 |
|  | C10296 |  |  | Early HER2 positive breast cancer Initial treatment (weekly regimen) Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant); 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; AND Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance. HER2 positivity must be demonstrated by in situ hybridisation (ISH). Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10296 |
| Trastuzumab emtansine | C10214 |  |  | Metastatic (Stage IV) HER2 positive breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for metastatic (Stage IV) HER2 positive breast cancer; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND The treatment must be as monotherapy; 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. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. The treatment must not exceed a lifetime total of one continuous course for this PBS indication. | Compliance with Authority Required procedures |
|  | C10255 |  |  | Early HER2 positive breast cancer Initial adjuvant treatment The treatment must be prescribed within 12 weeks after surgery; AND Patient must have, prior to commencing treatment with this drug, evidence of residual invasive cancer in the breast and/or axillary lymph nodes following completion of surgery, as demonstrated by a pathology report; AND Patient must have completed systemic neoadjuvant therapy that included trastuzumab and taxane-based chemotherapy prior to surgery; 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; AND The treatment must not extend beyond 42 weeks (14 cycles) duration under the initial and the continuing treatment restrictions combined. Authority applications for initial treatment must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Early Breast Cancer - PBS Supporting Information Form which includes details from the pathology report from an approved pathology authority demonstrating evidence of residual invasive carcinoma in the breast and/or axillary lymph nodes following completion of surgery. | Compliance with Written Authority Required procedures |
|  | C10273 |  |  | Early HER2 positive breast cancer Grandfather adjuvant treatment Patient must have received non-PBS-subsidised treatment with this drug as adjuvant treatment of early HER2 positive breast cancer prior to 1 April 2020; AND The treatment must have been prescribed within 12 weeks after surgery prior to commencing treatment with this drug; AND Patient must have, prior to commencing treatment with this drug, evidence of residual invasive cancer in the breast and/or axillary lymph nodes following completion of surgery, as demonstrated by a pathology report; AND Patient must have completed systemic neoadjuvant therapy that included trastuzumab and taxane-based chemotherapy prior to surgery; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; 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; AND The treatment must not extend beyond 42 weeks (14 cycles) duration using non-PBS-subsidised and PBS-subsidised drug supply obtained under the grandfather restriction and the continuing treatment restrictions combined. Authority applications for grandfather treatment must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Early Breast Cancer - PBS Supporting Information Form which includes details from the pathology report from an approved pathology authority demonstrating evidence of residual invasive carcinoma in the breast and/or axillary lymph nodes following completion of surgery and the number of non-PBS-subsidised cycles of treatment received by the patient. | Compliance with Written Authority Required procedures |
|  | C10295 |  |  | Early HER2 positive breast cancer Continuing adjuvant 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 not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND The treatment must not extend beyond 42 weeks (14 cycles) duration under the initial and the continuing treatment restrictions combined. | Compliance with Authority Required procedures |
|  | C10510 |  |  | 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; AND The condition must have progressed following treatment with pertuzumab and trastuzumab in combination; OR The condition must have progressed during or within 6 months of completing adjuvant therapy with trastuzumab; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be as monotherapy; 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 in writing and must include: (a) a completed authority prescription form; and (b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes: (i) details 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 tick a box to state the person has Stage IV disease; (ii) dates of treatment with trastuzumab and pertuzumab; and (iii) date of demonstration of progression following treatment with trastuzumab and pertuzumab; or (iv) date of demonstration of progression and date of completion of adjuvant trastuzumab treatment. 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. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval. | Compliance with Written Authority Required procedures |
| Travoprost with timolol | C4343 |  |  | Elevated intra-ocular pressure The condition must have been inadequately controlled with monotherapy; AND Patient must have open-angle glaucoma; OR Patient must have ocular hypertension. |  |
| C5038 |  |  | Elevated intra-ocular pressure The condition must have been inadequately controlled with monotherapy; AND Patient must have open-angle glaucoma; OR Patient must have ocular hypertension. |  |
| Triamcinolone | C4924 |  |  | Corticosteroid-responsive dermatoses |  |
| C6209 |  |  | Local intra-articular or peri-articular infiltration |  |
| C6210 |  |  | Keloid |  |
| C6211 |  |  | Chronic discoid lupus erythematosus |  |
| C6237 |  |  | Keloid |  |
| C6253 |  |  | Alopecia areata |  |
| C6254 |  |  | Granulomata The condition must be dermal. |  |
| C6255 |  |  | Lichen simplex chronicus |  |
| C6268 |  |  | Local intra-articular or peri-articular infiltration |  |
| C6269 |  |  | Necrobiosis lipoidica |  |
| C6281 |  |  | Lichen planus hypertrophic |  |
| C6287 |  |  | Psoriasis |  |
| C6291 |  |  | Lichen planus hypertrophic |  |
| Trifluridine with tipiracil | C8183 |  |  | Metastatic colorectal cancer  Continuing treatment  Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition; AND  Patient must not develop progressive disease whilst 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 8183 |
|  | C10252 |  |  | Metastatic (Stage IV) adenocarcinoma of the stomach or gastro-oesophageal junction Initial treatment Patient must have a WHO performance status of 1 or less; AND Patient must have previously received at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum and either a taxane or irinotecan; AND The treatment must be the sole PBS-subsidised therapy for this condition. The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 10252 |
|  | C10309 |  |  | Metastatic colorectal cancer Initial treatment Patient must have a WHO performance status of 1 or less; AND Patient must have previously received treatment with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapies, an anti-vascular endothelial growth factor (anti-VEGF) agent and an anti-epidermal growth factor receptor (anti-EGFR) agent for this condition; OR Patient must not be a suitable candidate for treatment with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapies, an anti-VEGF agent and an anti-EGFR agent for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition. The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 10309 |
|  | C10310 |  |  | Metastatic (Stage IV) adenocarcinoma of the stomach or gastro-oesophageal junction Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop progressive disease whilst 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 10310 |
| Triglycerides, long chain with glucose polymer | C4438 |  |  | Proven inborn errors of protein metabolism Patient must be unable to meet their energy requirements with permitted food and formulae. |  |
| Triglycerides, medium chain | C6134 |  |  | Chylothorax | Compliance with Authority Required procedures - Streamlined Authority Code 6134 |
| C6135 |  |  | Cerebrospinal fluid glucose transporter defect Patient must require a ketogenic diet. | Compliance with Authority Required procedures - Streamlined Authority Code 6135 |
| C6146 |  |  | Long chain fatty acid oxidation disorders | Compliance with Authority Required procedures - Streamlined Authority Code 6146 |
| C6147 |  |  | Ketogenic diet Patient must have intractable seizures requiring treatment with a ketogenic diet; OR Patient must have a glucose transport protein defect; OR Patient must have pyruvate dehydrogenase deficiency. | Compliance with Authority Required procedures - Streamlined Authority Code 6147 |
| C6155 |  |  | Intractable childhood epilepsy Patient must require a ketogenic diet. | Compliance with Authority Required procedures - Streamlined Authority Code 6155 |
| C6164 |  |  | Fat malabsorption The condition must be due to liver disease; OR The condition must be due to short gut syndrome; OR The condition must be due to cystic fibrosis; OR The condition must be due to gastrointestinal disorders. | Compliance with Authority Required procedures - Streamlined Authority Code 6164 |
| C6181 |  |  | Chylous ascites | Compliance with Authority Required procedures - Streamlined Authority Code 6181 |
| C6191 |  |  | Dietary management of conditions requiring a source of medium chain triglycerides Patient must have chylous ascites; OR Patient must have chylothorax; OR Patient must have hyperlipoproteinaemia type 1; OR Patient must have long chain fatty acid oxidation disorders; OR Patient must have fat malabsorption due to liver disease; OR Patient must have fat malabsorption due to short gut syndrome; OR Patient must have fat malabsorption due to cystic fibrosis; OR Patient must have fat malabsorption due to gastrointestinal disorders. | Compliance with Authority Required procedures - Streamlined Authority Code 6191 |
| C6203 |  |  | Hyperlipoproteinaemia type 1 | Compliance with Authority Required procedures - Streamlined Authority Code 6203 |
| Triglycerides, medium chain and long chain with glucose polymer | C4438 |  |  | Proven inborn errors of protein metabolism Patient must be unable to meet their energy requirements with permitted food and formulae. |  |
| Triglycerides - medium chain, formula | C4651 |  |  | Hyperlipoproteinaemia type 1 |  |
| C4652 |  |  | Chylous ascites |  |
| C4653 |  |  | Chylothorax |  |
| C4659 |  |  | Long chain fatty acid oxidation disorders |  |
| C4660 |  |  | Dietary management of conditions requiring a source of medium chain triglycerides Patient must have fat malabsorption due to liver disease; OR Patient must have fat malabsorption due to short gut syndrome; OR Patient must have fat malabsorption due to cystic fibrosis; OR Patient must have fat malabsorption due to gastrointestinal disorders. |  |
| C5541 |  |  | Dietary management of conditions requiring a source of medium chain triglycerides Patient must have fat malabsorption due to liver disease; OR Patient must have fat malabsorption due to short gut syndrome; OR Patient must have fat malabsorption due to cystic fibrosis; OR Patient must have fat malabsorption due to gastrointestinal disorders. |  |
| C6136 |  |  | Long chain fatty acid oxidation disorders | Compliance with Authority Required procedures - Streamlined Authority Code 6136 |
| C6156 |  |  | Hyperlipoproteinaemia type 1 | Compliance with Authority Required procedures - Streamlined Authority Code 6156 |
| C6165 |  |  | Chylous ascites | Compliance with Authority Required procedures - Streamlined Authority Code 6165 |
| C6173 |  |  | Fat malabsorption The condition must be due to liver disease; OR The condition must be due to short gut syndrome; OR The condition must be due to cystic fibrosis; OR The condition must be due to gastrointestinal disorders. | Compliance with Authority Required procedures - Streamlined Authority Code 6173 |
| C6192 |  |  | Chylothorax | Compliance with Authority Required procedures - Streamlined Authority Code 6192 |
| Trimethoprim |  | P4243 | CN4243 | Prophylaxis of urinary tract infection | Compliance with Authority Required procedures - Streamlined Authority Code 4243 |
|  | P6163 |  | Prostatitis |  |
| Trimethoprim with sulfamethoxazole |  | P6201 | CN6201 | Prophylaxis of Pneumocystis jiroveci pneumonia | Compliance with Authority Required procedures - Streamlined Authority Code 6201 |
| Triptorelin | C5046 |  |  | Assisted Reproductive Technology The treatment must be for prevention of premature luteinisation and ovulation; AND Patient must be undergoing controlled ovarian stimulation; AND Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule. | Compliance with Authority Required procedures - Streamlined Authority Code 5046 |
| C6409 |  |  | Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate |  |
| Tropisetron | C4077 |  |  | Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle. |  |
| C5749 |  |  | Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle. |  |
| Tyrosine with carbohydrate | C4295 |  |  | Phenylketonuria |  |
| Umeclidinium | C4516 |  |  | Chronic obstructive pulmonary disease (COPD) |  |
| Umeclidinium with vilanterol | C7798 |  |  | Chronic obstructive pulmonary disease (COPD)  Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR  Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR  Patient must have been stabilised on a combination of a LAMA and a LABA. | Compliance with Authority Required procedures - Streamlined Authority Code 7798 |
| Upadacitinib | C8638 | P8638 |  | Severe active rheumatoid arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
|  | C8680 | P8680 |  | Severe active rheumatoid arthritis Continuing and Initial Grandfathered patients treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; OR Patient must have received insufficient treatment with this drug to complete 24 weeks of treatment under the Initial treatment - Grandfathered patients; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. Patient must be aged 18 years or older. | Compliance with Authority Required procedures |
|  | C10340 | P10340 |  | Severe active rheumatoid arthritis Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. 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, ESR and/or CRP must be no more than 4 weeks old at the time of application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
|  | C10341 | P10341 |  | Severe active rheumatoid arthritis Initial treatment - Grandfathered patients Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 May 2020; AND Patient must be receiving treatment with this drug for this condition at the time of application; AND Patient must have failed to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) prior to initiating non-PBS-subsidised treatment with this drug for this condition. This must have included at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must have been methotrexate at a dose of at least 20 mg weekly and one of which must have been: (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 to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs prior to initiating non-PBS-subsidised treatment with this drug for this condition. If methotrexate was contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or could not be tolerated at a 20 mg weekly dose, this intensive treatment must have included 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 to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs prior to initiating non-PBS-subsidised treatment with this drug for this condition. If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine were contraindicated according to the relevant TGA-approved Product Information or could not be tolerated at the doses specified above, the intensive treatment must have included at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs used in place of the DMARDS which were contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to have achieved an adequate response to DMARD treatment prior to initiating non-PBS-subsidised treatment with this drug for this condition: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. All applications for treatment with this drug for this condition under this restriction must include baseline joint count and ESR and/or CRP as determined at the completion of a 6 month intensive DMARD trial but prior to ceasing DMARD therapy. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. | Compliance with Written Authority Required procedures |
|  | C10356 | P10356 |  | Severe active rheumatoid arthritis Continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. 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 has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
|  | C10376 | P10376 |  | Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, conducted within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. | Compliance with Written Authority Required procedures |
|  | C10393 | P10393 |  | Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with 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 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
| Ursodeoxycholic acid | C9032 |  |  | Primary biliary cholangitis (previously known as Primary biliary cirrhosis) | Compliance with Authority Required procedures - Streamlined Authority Code 9032 |
| Ustekinumab | C6696 | P6696 |  | Severe chronic plaque psoriasis Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND The treatment must be as systemic monotherapy (other than methotrexate). Must be treated by a dermatologist. | Compliance with Authority Required procedures |
|  | C8891 | P8891 |  | Severe chronic plaque psoriasis Continuing treatment, Whole body Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C8918 | P8918 |  | Severe chronic plaque psoriasis Initial treatment - Initial 1, Face, hand, foot (new patient) Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 1 month old at the time of application. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to 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 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 |
|  | C8919 | P8919 |  | 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 28 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 1 month old at the time of application. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the 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 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 |
|  | C8963 | P8963 |  | 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 28 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 1 month old at the time of application. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the 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 |
|  | C8964 | P8964 |  | Severe chronic plaque psoriasis Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years ) restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; AND The treatment must be as systemic monotherapy (other than methotrexate); AND The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction. Must be treated by a dermatologist. | Compliance with Authority Required procedures |
|  | C8986 | P8986 |  | Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 1 month old at the time of application. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised. 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 |
|  | C8987 | P8987 |  | Severe chronic plaque psoriasis Continuing treatment, Face, hand, foot Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C9063 | P9063 |  | Severe psoriatic arthritis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. | Compliance with Authority Required procedures |
|  | C9116 | P9116 |  | Severe psoriatic arthritis Continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C9122 | P9122 |  | Severe psoriatic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be aged 18 years or older. 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 |
|  | C9160 | P9160 |  | Severe psoriatic arthritis Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; AND The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
|  | C9175 | P9175 |  | Severe psoriatic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have 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 28 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C9176 | P9176 |  | Severe psoriatic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be aged 18 years or older. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C9655 | P9655 |  | Severe Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment; and (iv) the details of prior biological medicine treatment including the details of date and duration of treatment. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats. A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised. Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. 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 |
|  | C9656 | P9656 |  | Severe Crohn disease Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND Patient must have evidence of intestinal inflammation; OR Patient must be assessed clinically as being in a high faecal output state; OR Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient; AND The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iii) the date of the most recent clinical assessment. 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. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats. A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised. Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. 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 continuing treatment restriction. 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 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. 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 |
|  | C9657 | P9657 |  | Severe Crohn disease Continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment. All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. An application for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be conducted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, 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. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks. Where an inadequate number of repeats are requested at the time of the application to complete a course of 24 weeks treatment, authority approvals for sufficient repeats to complete 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend continuing treatment beyond 24 months. | Compliance with Written Authority Required procedures |
|  | C9710 | P9710 |  | Severe Crohn disease Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must be aged 18 years or older. Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 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. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iv) the date of the most recent clinical assessment. Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following: (a) patient must have evidence of intestinal inflammation; (b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient. Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats. A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised. Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month 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 Department of Human Services 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 continuing treatment restriction. 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 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 |
|  | C9711 | P9711 |  | Severe Crohn disease Balance of supply Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment. | Compliance with Authority Required procedures |
|  | C9875 | P9875 |  | 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 28 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or 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 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. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current 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 |
|  | C9930 | P9930 |  | 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 28 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or 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. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current 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 |
| Valaciclovir | C5940 | P5940 |  | Recurrent moderate to severe genital herpes Suppressive therapy Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 5940 |
| C5960 | P5960 |  | Initial moderate to severe genital herpes Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 5960 |
| C5961 | P5961 |  | Recurrent moderate to severe genital herpes Episodic treatment Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 5961 |
| C5962 | P5962 |  | Herpes zoster The treatment must be administered within 72 hours of the onset of the rash. | Compliance with Authority Required procedures - Streamlined Authority Code 5962 |
| C5968 | P5968 |  | Herpes zoster ophthalmicus | Compliance with Authority Required procedures - Streamlined Authority Code 5968 |
| C5975 |  |  | Cytomegalovirus infection and disease Prophylaxis Patient must have undergone a renal transplant; AND Patient must be at risk of cytomegalovirus disease. | Compliance with Authority Required procedures - Streamlined Authority Code 5975 |
| C9267 |  |  | Cytomegalovirus infection and disease Prophylaxis Patient must have undergone a renal transplant; AND Patient must be at risk of cytomegalovirus disease. | Compliance with Authority Required procedures - Streamlined Authority Code 9267 |
| Valganciclovir | C4980 |  |  | Cytomegalovirus retinitis Patient must have HIV infection. | Compliance with Authority Required procedures - Streamlined Authority Code 4980 |
| C4989 |  |  | Cytomegalovirus infection and disease Prophylaxis Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease. | Compliance with Authority Required procedures - Streamlined Authority Code 4989 |
| C9316 |  |  | Cytomegalovirus infection and disease Prophylaxis Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease. | Compliance with Authority Required procedures - Streamlined Authority Code 9316 |
| Valine with carbohydrate | C5571 |  |  | Maple syrup urine disease |  |
| Valsartan with hydrochlorothiazide | C4361 |  |  | Hypertension The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an angiotensin II antagonist; OR The condition must be inadequately controlled with a thiazide diuretic. |  |
| C4374 |  |  | Hypertension The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an angiotensin II antagonist; OR The condition must be inadequately controlled with a thiazide diuretic. |  |
| Vancomycin | C5636 |  |  | Antibiotic associated pseudomembranous colitis The condition must be due to Clostridium difficile; AND Patient must have an intolerance to metronidazole. | Compliance with Authority Required procedures |
| C5660 |  |  | Antibiotic associated pseudomembranous colitis The condition must be due to Clostridium difficile; AND The condition must be unresponsive to metronidazole. | Compliance with Authority Required procedures |
| C5716 | P5716 |  | Endophthalmitis |  |
| C5717 | P5717 |  | Endocarditis The treatment must be for prophylaxis; AND Patient must be hypersensitive to penicillin. |  |
| C5769 | P5769 |  | Infection The treatment must be initiated in a hospital; AND The condition must be one in which vancomycin is an appropriate antibiotic. |  |
| C5801 |  |  | Endocarditis The treatment must be for prophylaxis; AND Patient must be hypersensitive to penicillin. |  |
| Varenicline | C6871 |  |  | Nicotine dependence Commencement of a short-term (12 weeks or 24 weeks) course of treatment The treatment must be as an aid to achieving abstinence from smoking; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have indicated they are ready to cease smoking; AND Patient must not receive more than 24 weeks of PBS-subsidised treatment with this drug per 12-month period. Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated. Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated. Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested. | Compliance with Authority Required procedures - Streamlined Authority Code 6871 |
| C6885 | P6885 |  | Nicotine dependence Completion of a short-term (24 weeks) course of treatment The treatment must be as an aid to achieving abstinence from smoking; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment; AND Patient must have ceased smoking in the process of completing an initial 12-weeks or ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment. Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program. | Compliance with Authority Required procedures - Streamlined Authority Code 6885 |
| C7483 | P7483 |  | Nicotine dependence Continuation of a short-term (12 weeks or 24 weeks) course of treatment The treatment must be as an aid to achieving abstinence from smoking; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously received treatment with this drug during this current course of treatment. Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program. | Compliance with Authority Required procedures - Streamlined Authority Code 7483 |
| Vemurafenib | C6013 | P6013 |  | Unresectable Stage III or Stage IV malignant melanoma Continuing treatment Patient must have previously been issued with an authority prescription for this drug; AND Patient must have stable or responding disease. | Compliance with Authority Required procedures - Streamlined Authority Code 6013 |
|  | C10157 | P10157 |  | Unresectable Stage III or Stage IV malignant melanoma Initial treatment The condition must be positive for a BRAF V600 mutation; AND The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; OR Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal; AND Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage IIIB, IIIC or IIID melanoma; AND Patient must have a WHO performance status of 2 or less. | Compliance with Authority Required procedures - Streamlined Authority Code 10157 |
| Venetoclax | C8579 |  |  | Chronic lymphocytic leukaemia (CLL) Grandfathered treatment Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 March 2019; AND Patient must have been considered unsuitable for treatment or retreatment with a purine analogue prior to initiating non-PBS subsidised treatment with this drug for this condition; AND The condition must have relapsed or be refractory to at least one prior therapy; AND Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with rituximab for up to a maximum of 6 cycles, followed by monotherapy; AND The treatment must be ceased on disease progression or on completion of 24 months of PBS-subsidised treatment with this drug for this condition, whichever comes first. A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria. | Compliance with Authority Required procedures |
|  | C8586 |  |  | Chronic lymphocytic leukaemia (CLL)  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be in combination with rituximab for up to a maximum of 6 cycles, followed by monotherapy; AND  The treatment must be ceased on disease progression or on completion of 24 months of PBS-subsidised treatment with this drug for this condition, whichever comes first. | Compliance with Authority Required procedures |
|  | C8607 |  |  | Chronic lymphocytic leukaemia (CLL)  Initial treatment - Dose titration  Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must be considered unsuitable for treatment or retreatment with a purine analogue; AND  The condition must have relapsed or be refractory to at least one prior therapy; AND  Patient must have a WHO performance status of 0 or 1; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  The treatment must be used as monotherapy for this condition under this restriction.  A patient is considered unsuitable for treatment or retreatment with a purine analogue as demonstrated by at least one of the following:  a) Failure to respond (stable disease or disease progression on treatment), or a progression-free interval of less than 3 years from treatment with a purine analogue-based therapy and anti-CD20-containing chemoimmunotherapy regimen after at least two cycles;  b) Age is 70 years or older;  c) Age is 65 years or older and the presence of comorbidities (Cumulative Illness Rating Scale of 6 or greater, or creatinine clearance of less than 70 mL/min) that might place the patient at an unacceptable risk for treatment-related toxicity with purine analogue-based therapy, provided they have received one or more prior treatment including at least two cycles of an alkylating agent-based (or purine analogue-based) anti-CD20 antibody-containing chemoimmunotherapy regimen;  d) History of purine analogue-associated autoimmune anaemia or autoimmune thrombocytopenia;  e) Evidence of one or more 17p chromosomal deletions demonstrated by fluorescence in situ hybridisation (FISH). | Compliance with Authority Required procedures |
|  | C8699 |  |  | Chronic lymphocytic leukaemia (CLL)  Initial treatment - Extension of dose titration Patient must have experienced a treatment interruption during the PBS-subsidised dose titration 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 used as monotherapy for this condition under this restriction. | Compliance with Authority Required procedures |
| Venlafaxine | C5650 |  |  | Major depressive disorders |  |
| Vigabatrin | C4929 |  |  | Epileptic seizures The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs. | Compliance with Authority Required procedures - Streamlined Authority Code 4929 |
| Vildagliptin | C6346 |  |  | Diabetes mellitus type 2 The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 6346 |
| C6363 |  |  | Diabetes mellitus type 2 The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 6363 |
| C6376 |  |  | Diabetes mellitus type 2 The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 6376 |
| Vildagliptin with metformin | C6333 |  |  | Diabetes mellitus type 2 Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. | Compliance with Authority Required procedures - Streamlined Authority Code 6333 |
| C6344 |  |  | Diabetes mellitus type 2 The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. | Compliance with Authority Required procedures - Streamlined Authority Code 6344 |
| C6357 |  |  | Diabetes mellitus type 2 Continuing Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and vildagliptin. | Compliance with Authority Required procedures - Streamlined Authority Code 6357 |
| C6443 |  |  | Diabetes mellitus type 2 The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 6443 |
| Vinorelbine | C4242 |  |  | Locally advanced or metastatic non-small cell lung cancer | Compliance with Authority Required procedures |
| C4272 |  |  | Advanced breast cancer Patient must have failed standard prior therapy, which includes an anthracycline. | Compliance with Authority Required procedures |
| Vismodegib | C7491 |  |  | Metastatic or locally advanced basal cell carcinoma Initial treatment or Continuing treatment – balance of supply Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| C7540 |  |  | Metastatic or locally advanced basal cell carcinoma 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 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 in writing and must include: a) A completed authority prescription form; and b) A completed Basal Cell Carcinoma Continuing PBS Authority Application Form - Supporting Information Form; and c) A confirmation statement from the treating doctor that the disease has not progressed; and d) In patients with locally advanced BCC, a letter from a surgically qualified clinician demonstrating that the condition remains inappropriate for surgery; or a letter from a radiation oncologist demonstrating 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. It is recommended that an application is submitted to the Department of Human Services 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. 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 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 | Compliance with Written Authority Required procedures |
| C7557 |  |  | Metastatic or locally advanced basal cell carcinoma 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 in writing and must include: a) A completed authority prescription form; and b) A completed Basal Cell Carcinoma Initial PBS Authority Application Form - Supporting Information Form; and c) A histological confirmation of BCC and whether the condition is metastatic or locally advanced; and d) A letter from a surgically qualified clinician demonstrating inappropriateness for surgery for patients with locally advanced BCC; and e) A letter from a radiation oncologist demonstrating inappropriateness for curative radiotherapy for patients with locally advanced BCC; and f) A signed patient acknowledgement. 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. It is recommended that an application is submitted to the Department of Human Services 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. 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 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. | Compliance with Written Authority Required procedures |
| Vitamins, minerals and trace elements formula | C7275 |  |  | Dietary management of conditions requiring a highly restrictive therapeutic diet Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet; AND Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations. Patient must be aged 3 years or older. |  |
| Vitamins, minerals and trace elements with carbohydrate | C6152 |  |  | Dietary management of conditions requiring a highly restrictive therapeutic diet Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet; AND Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations. Patient must be an infant or a child. |  |
| C6159 |  |  | Dietary management of conditions requiring a highly restrictive therapeutic diet Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet; AND Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations. Patient must be aged 3 years or older. |  |
| Voriconazole | C4683 | P4683 |  | Serious invasive mycosis infections Treatment and maintenance therapy The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis. | Compliance with Authority Required procedures |
| C4685 | P4685 |  | Prophylaxis of invasive fungal infections including both yeasts and moulds Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre) for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or, extensive chronic GVHD, whilst receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant; OR Patient must be undergoing allogeneic haematopoietic stem cell transplant using either bone marrow from an unrelated donor or umbilical cord blood (related or unrelated), and, be considered to be at high risk of developing an invasive fungal infection during the neutropenic phase prior to engraftment. | Compliance with Authority Required procedures |
| C5624 |  |  | Serious fungal infections Treatment and maintenance therapy The condition must be caused by Scedosporium species; OR The condition must caused by Fusarium species. | Compliance with Authority Required procedures |
| C5692 | P5692 |  | Serious Candida infections Treatment and maintenance therapy The condition must be caused by species not susceptible to fluconazole; OR The condition must be resistant to fluconazole; OR Patient must be unable to tolerate fluconazole. | Compliance with Authority Required procedures |
| C5725 | P5725 |  | Definite or probable invasive aspergillosis Treatment and maintenance therapy Patient must be immunocompromised. | Compliance with Authority Required procedures |
| C5734 |  |  | Serious invasive mycosis infections Treatment and maintenance therapy The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis. | Compliance with Authority Required procedures |
| C5748 | P5748 |  | Serious fungal infections Treatment and maintenance therapy The condition must be caused by Scedosporium species; OR The condition must caused by Fusarium species. | Compliance with Authority Required procedures |
| C5813 |  |  | Definite or probable invasive aspergillosis Treatment and maintenance therapy Patient must be immunocompromised. | Compliance with Authority Required procedures |
| C5814 |  |  | Serious Candida infections Treatment and maintenance therapy The condition must be caused by species not susceptible to fluconazole; OR The condition must be resistant to fluconazole; OR Patient must be unable to tolerate fluconazole. | Compliance with Authority Required procedures |
| Vorinostat | C6957 | P6957 |  | 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 in writing and must include: (a) a completed authority prescription form; and (b) a completed cutaneous T-cell lymphoma (CTCL) initial PBS Authority Application - Supporting Information Form. | Compliance with Authority Required procedures |
| C6964 | P6964 |  | 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 progressive disease 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 |
| Whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose | C6190 |  |  | Chronic renal failure Patient must be an infant or a young child. Patient must require treatment with a low protein and a low phosphorus diet; OR Patient must require treatment with a low protein, low phosphorus and low potassium diet. | Compliance with Authority Required procedures - Streamlined Authority Code 6190 |
| Whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose | C6190 |  |  | Chronic renal failure Patient must be an infant or a young child. Patient must require treatment with a low protein and a low phosphorus diet; OR Patient must require treatment with a low protein, low phosphorus and low potassium diet. | Compliance with Authority Required procedures - Streamlined Authority Code 6190 |
| Zidovudine | C4454 |  |  | HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 4454 |
| C4512 |  |  | HIV infection Initial Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 4512 |
| Ziprasidone | C4246 |  |  | Schizophrenia | Compliance with Authority Required procedures - Streamlined Authority Code 4246 |
| C5742 |  |  | Acute mania or mixed episodes The condition must be associated with bipolar I disorder; AND The treatment must be as monotherapy; AND The treatment must be limited to up to 6 months per episode. | Compliance with Authority Required procedures - Streamlined Authority Code 5742 |
| Zoledronic acid | C5605 |  |  | Bone metastases The condition must be due to breast cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 5605 |
| C5703 |  |  | Bone metastases The condition must be due to castration-resistant prostate cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 5703 |
| C5704 |  |  | Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 5704 |
| C5710 |  |  | Symptomatic Paget disease of bone Only 1 treatment each year per patient will be PBS-subsidised | Compliance with Authority Required procedures - Streamlined Authority Code 5710 |
| C5735 |  |  | Multiple myeloma | Compliance with Authority Required procedures - Streamlined Authority Code 5735 |
| C6308 |  |  | Corticosteroid-induced osteoporosis Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy; AND Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition; AND Patient must not receive more than one PBS-subsidised treatment per year. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 6308 |
| C6313 |  |  | Osteoporosis Patient must be aged 70 years or older. Patient must have a Bone Mineral Density (BMD) T-score of -3.0 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition; AND Patient must not receive more than one PBS-subsidised treatment per year. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 6313 |
| C6318 |  |  | Established osteoporosis Patient must have fracture due to minimal trauma; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition; AND Patient must not receive more than one PBS-subsidised treatment per year. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. | Compliance with Authority Required procedures - Streamlined Authority Code 6318 |
|  | C9268 |  |  | Multiple myeloma | Compliance with Authority Required procedures - Streamlined Authority Code 9268 |
|  | C9304 |  |  | Bone metastases The condition must be due to castration-resistant prostate cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 9304 |
|  | C9317 |  |  | Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 9317 |
|  | C9328 |  |  | Bone metastases The condition must be due to breast cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 9328 |
| Zolmitriptan | C5489 |  |  | Migraine attack The condition must have usually failed to respond to analgesics in the past. |  |
| Zonisamide | C4928 |  |  | Partial epileptic seizures The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs. | Compliance with Authority Required procedures - Streamlined Authority Code 4928 |

Note: The name of the listed drug is included in this table to assist in identifying the circumstances applying to the pharmaceutical benefits that have a particular drug.

Part 3—General statement for drugs for the treatment of hepatitis C

**1 Criteria for eligibility for drugs for the treatment of chronic hepatitis C**

The criteria for patient eligibility for drugs for the treatment of chronic hepatitis C are that:

1. the patient has been assessed in accordance with paragraph 2 of this Part; and
2. the patient is:
   1. treated by a medical practitioner or an authorised nurse practitioner who is experienced in the treatment of patients with chronic hepatitis C infection; or
   2. treated by a medical practitioner or an authorised nurse practitioner in consultation with:
   3. a gastroenterologist; or
   4. a hepatologist; or
   5. an infectious diseases physician.

**2 Assessment of patient**

For the purpose of subparagraph 1(2) of this Part, the patient has been assessed if the treating medical practitioner has:

1. documented the following information in the patient’s medical records:
   * + - 1. evidence of chronic hepatitis C infection; and
         2. where possible, evidence of the patient’s hepatitis C virus genotype; and
2. chosen a regimen in accordance with paragraph 3 of this Part; and
3. collected the following information for the purposes of the authority application:
   * + - 1. whether the patient is:
     1. cirrhotic; or
     2. non-cirrhotic
        + 1. details of the previous treatment regimen (**only** for requests for sofosbuvir with velpatasvir and voxilaprevir or glecaprevir with pibrentasvir for 16 weeks’ treatment in patients who have previously failed a treatment with a regimen containing an NS5A inhibitor).
4. In this paragraph, evidence of chronic hepatitis C infection is documentation of:
5. repeat test results showing antibody to hepatitis C virus (anti-HCV) positive; and
6. test result showing hepatitis C virus ribonucleic acid (RNA) positive.

**3 Treatment regimen**

For the purpose of subparagraph 2(2) of this Part, the treating medical practitioner has chosen a regimen in accordance with this paragraph if the patient:

1. is a kind of patient mentioned for an Item in column 2 of the following table; and
2. is to receive one of the regimens mentioned in column 3 of the same Item of the following table.

| **Item** | **Kind of patient** | **Regimen** |
| --- | --- | --- |
| 1 | Patient:   1. all genotypes (pan-genotypic); and 2. who is treatment naïve; and 3. who is non-cirrhotic. | Either:   1. SOFOSBUVIR with VELPATASVIR for 12 weeks; or 2. GLECAPREVIR with PIBRENTASVIR for 8 weeks. |
| 2 | Patient:   1. all genotypes (pan-genotypic); and 2. who is treatment experienced; and 3. who is non-cirrhotic. | Either:   1. SOFOSBUVIR with VELPATASVIR for 12 weeks; or 2. SOFOSBUVIR with VELPATASVIR and VOXILAPREVIR for 12 weeks; or 3. GLECAPREVIR with PIBRENTASVIR for 8 weeks; or 4. GLECAPREVIR with PIBRENTASVIR for 12 weeks; or 5. GLECAPREVIR with PIBRENTASVIR 16 weeks. |
| 3 | Patient:   1. with Genotype 1; and 2. who is treatment naïve; and 3. who is non-cirrhotic. | Either:   1. LEDIPASVIR with SOFOSBUVIR for 8 weeks; or 2. LEDIPASVIR with SOFOSBUVIR for 12 weeks; or 3. DACLATASVIR and SOFOSBUVIR for 12 weeks; or 4. GRAZOPREVIR with ELBASVIR for 12 weeks. |
| 4 | Patient:   1. with Genotype 1; and 2. who is treatment experienced; and 3. who is non-cirrhotic. | Either:   1. LEDIPASVIR with SOFOSBUVIR for 12 weeks; or 2. DACLATASVIR and SOFOSBUVIR for 12 weeks; or 3. DACLATASVIR and SOFOSBUVIR for 24 weeks; or 4. GRAZOPREVIR with ELBASVIR for 12 weeks; or 5. GRAZOPREVIR with ELBASVIR and RIBAVIRIN for 16 weeks. |
| 5 | Patient:   1. with Genotype 2; and 2. who is treatment naïve; and 3. who is non-cirrhotic. | SOFOSBUVIR and RIBAVIRIN for 12 weeks. |
| 6 | Patient:   1. with Genotype 2; and 2. who is treatment experienced; and 3. who is non-cirrhotic. | SOFOSBUVIR and RIBAVIRIN for 12 weeks. |
| 7 | Patient:   1. with Genotype 3; and 2. who is treatment naïve; and 3. who is non-cirrhotic. | Either:   1. DACLATASVIR and SOFOSBUVIR for 12 weeks; or 2. SOFOSBUVIR and RIBAVIRIN for 24 weeks. |
| 8 | Patient:   1. with Genotype 3; and 2. who is treatment experienced; and 3. who is non-cirrhotic. | Either:   1. DACLATASVIR and SOFOSBUVIR for 12 weeks; or 2. SOFOSBUVIR and RIBAVIRIN for 24 weeks. |
| 9 | Patient:   1. with Genotype 4; and 2. who is treatment naïve; and 3. who is non-cirrhotic. | GRAZOPREVIR with ELBASVIR for 12 weeks. |
| 10 | Patient:   1. with Genotype 4; and 2. who is treatment experienced; and 3. who is non-cirrhotic. | Either:   1. GRAZOPREVIR with ELBASVIR for 12 weeks; or 2. GRAZOPREVIR with ELBASVIR and RIBAVIRIN for 16 weeks. |
| 11 | Patient:   1. with:    1. Genotype 5; or    2. Genotype 6; and 2. who is treatment naïve; and 3. who is non-cirrhotic. | Refer to item 1 above (pan-genotypic, treatment naïve and non-cirrhotic regimens). |
| 12 | Patient:   1. with: 2. Genotype 5; or 3. Genotype 6; and 4. who is treatment experienced; and 5. who is non-cirrhotic. | Refer to item 1 above (pan-genotypic, treatment experienced and non-cirrhotic regimens). |
| 13 | Patient:   1. all genotypes (pan-genotypic); and 2. who is treatment naïve; and 3. who is cirrhotic. | Either:   1. SOFOSBUVIR with VELPATASVIR for 12 weeks; or 2. GLECAPREVIR with PIBRENTASVIR for 12 weeks. |
| 14 | Patient:   1. all genotypes (pan-genotypic); and 2. who is treatment experienced; and 3. who is cirrhotic. | Either:   1. SOFOSBUVIR with VELPATASVIR for 12 weeks; or 2. SOFOSBUVIR with VELPATASVIR and VOXILAPREVIR for 12 weeks; or 3. GLECAPREVIR with PIBRENTASVIR for 12 weeks; or 4. GLECAPREVIR with PIBRENTASVIR 16 weeks. |
| 15 | Patient:   1. with Genotype 1; and 2. who is treatment naïve; and 3. who is cirrhotic. | Either:   1. LEDIPASVIR with SOFOSBUVIR for 12 weeks; or 2. DACLATASVIR and SOFOSBUVIR and RIBAVIRIN for 12 weeks; or 3. DACLATASVIR and SOFOSBUVIR for 24 weeks; or 4. GRAZOPREVIR with ELBASVIR for 12 weeks. |
| 16 | Patient:   1. with Genotype 1; and 2. who is treatment experienced; and 3. who is cirrhotic. | Either:   1. LEDIPASVIR with SOFOSBUVIR for 24 weeks; or 2. DACLATASVIR and SOFOSBUVIR for 24 weeks; or 3. DACLATASVIR and SOFOSBUVIR and RIBAVIRIN for 12 weeks; or 4. GRAZOPREVIR with ELBASVIR for 12 weeks; or 5. GRAZOPREVIR with ELBASVIR and RIBAVIRIN for 16 weeks. |
| 17 | Patient:   1. with Genotype 2; and 2. who is treatment naïve; and 3. who is cirrhotic. | SOFOSBUVIR and RIBAVIRIN for 12 weeks. |
| 18 | Patient:   1. with Genotype 2; and 2. who is treatment experienced; and 3. who is cirrhotic. | SOFOSBUVIR and RIBAVIRIN for 12 weeks. |
| 19 | Patient:   1. with Genotype 3; and 2. who is treatment naïve; and 3. who is cirrhotic. | Either:   1. SOFOSBUVIR and RIBAVIRIN for 24 weeks; or 2. DACLATASVIR and SOFOSBUVIR for 24 weeks; or 3. DACLATASVIR and SOFOSBUVIR and RIBAVIRIN for 12 weeks; or 4. DACLATASVIR and SOFOSBUVIR and RIBAVIRIN for 24 weeks. |
| 20 | Patient:   1. with Genotype 3; and 2. who is treatment experienced; and 3. who is cirrhotic. | Either:   1. DACLATASVIR and SOFOSBUVIR for 24 weeks; or 2. SOFOSBUVIR and RIBAVIRIN for 24 weeks; or 3. DACLATASVIR and SOFOSBUVIR and RIBAVIRIN for 12 weeks; or 4. DACLATASVIR and SOFOSBUVIR and RIBAVIRIN for 24 weeks. |
| 21 | Patient:   1. with Genotype 4; and 2. who is treatment naïve; and 3. who is cirrhotic. | GRAZOPREVIR with ELBASVIR for 12 weeks. |
| 22 | Patient:   1. with Genotype 4; and 2. who is treatment experienced; and 3. who is cirrhotic. | Either:   1. GRAZOPREVIR with ELBASVIR for 12 weeks; or 2. GRAZOPREVIR with ELBASVIR and RIBAVIRIN for 16 weeks. |
| 23 | Patient:   1. with: 2. Genotype 5; or 3. Genotype 6; and 4. who is treatment naïve; and 5. who is cirrhotic. | Refer to item 13 above (pan-genotypic, treatment naïve and cirrhotic regimens). |
| 24 | Patient:   1. with: 2. Genotype 5; or 3. Genotype 6; and 4. who is treatment experienced; and 5. who is cirrhotic. | Refer to item 14 above (pan-genotypic, treatment experienced and cirrhotic regimens). |

Schedule 5—Schedule equivalent

(section 8A)

| **Listed Drug** | **Schedule Equivalent Group** | **Form** | **Manner of Administration** | **Brand** |
| --- | --- | --- | --- | --- |
| Abacavir with lamivudine | GRP-21981 | Tablet containing abacavir 600 mg (as hydrochloride) with lamivudine 300 mg | Oral | Abacavir/Lamivudine GH 600/300 |
|  |  | Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg | Oral | ABACAVIR/LAMIVUDINE 600/300 SUN Abacavir/Lamivudine Mylan Kivexa |
| Clopidogrel | GRP-15475 | Tablet 75 mg (as besilate) | Oral | BTC Clopidogrel Clopidogrel APOTEX Clopidogrel-GA Clopidogrel GH Clovix 75 Plidogrel |
|  |  | Tablet 75 mg (as hydrogen sulfate) | Oral | APO-Clopidogrel Blooms the Chemist Clopidogrel Clopidogrel AN Clopidogrel Sandoz Clopidogrel Sandoz Pharma Clopidogrel Winthrop Iscover Piax |
|  | GRP-17110 | Tablet 75 mg (as besilate) | Oral | BTC Clopidogrel Clopidogrel APOTEX Clopidogrel GH Clopidogrel-GA Clovix 75 Plidogrel |
|  |  | Tablet 75 mg (as hydrogen sulfate) | Oral | APO-Clopidogrel Blooms the Chemist Clopidogrel Clopidogrel AN Clopidogrel Sandoz Clopidogrel Sandoz Pharma Clopidogrel Winthrop Iscover Piax Plavicor 75 |
| Desvenlafaxine | GRP-16219 | Tablet (extended release) 100 mg (as succinate) | Oral | Pristiq |
|  |  | Tablet (modified release) 100 mg | Oral | DESVEN Desfax Desvenlafaxine Actavis Desvenlafaxine Sandoz |
|  |  | Tablet (modified release) 100 mg (as benzoate) | Oral | APO-Desvenlafaxine MR Desvenlafaxine GH XR |
|  | GRP-16220 | Tablet (extended release) 50 mg (as succinate) | Oral | Pristiq |
|  |  | Tablet (modified release) 50 mg | Oral | DESVEN Desfax Desvenlafaxine Actavis Desvenlafaxine Sandoz |
|  |  | Tablet (modified release) 50 mg (as benzoate) | Oral | APO-Desvenlafaxine MR Desvenlafaxine GH XR |
| Doxycycline | GRP-14639 | Capsule 100 mg (as hyclate) (containing enteric coated pellets) | Oral | Doryx Mayne Pharma Doxycycline |
|  |  | Tablet 100 mg (as hyclate) | Oral | Doxsig Doxycycline AN Doxylin 100 |
|  |  | Tablet 100 mg (as monohydrate) | Oral | APO-Doxycycline Doxycycline Sandoz |
|  | GRP-15635 | Capsule 50 mg (as hyclate) (containing enteric coated pellets) | Oral | Doryx Mayne Pharma Doxycycline |
|  |  | Tablet 50 mg (as hyclate) | Oral | Doxsig Doxycycline AN Doxylin 50 |
|  |  | Tablet 50 mg (as monohydrate) | Oral | APO-Doxycycline Doxycycline Sandoz Frakas |
| Epoprostenol | GRP-16914 | Powder for I.V. infusion 500 micrograms (as sodium) | Injection | EPOPROSTENOL SUN  Veletri |
|  |  | Powder for I.V. infusion 500 micrograms (as sodium) with 2 vials diluent 50 mL | Injection | Flolan |
|  | GRP-16976 | Powder for I.V. infusion 1.5 mg (as sodium) | Injection | EPOPROSTENOL SUN  Veletri |
|  |  | Powder for I.V. infusion 1.5 mg (as sodium) with 2 vials diluent 50 mL | Injection | Flolan |
| Esomeprazole | GRP-17061 | Capsule (enteric) 40 mg (as magnesium) | Oral | Esomeprazole ACTAVIS Noxicid Caps |
|  |  | Tablet (enteric coated) 40 mg (as magnesium trihydrate) | Oral | Esomeprazole Apotex Esomeprazole GH Esomeprazole GxP Esomeprazole RBX Esomeprazole SZ Esomeprazole Sandoz Nexazole Nexium Nexole Pharmacor Esomeprazole |
|  | GRP-17188 | Capsule (enteric) 20 mg (as magnesium) | Oral | Esomeprazole ACTAVIS Noxicid Caps |
|  |  | Tablet (enteric coated) 20 mg (as magnesium trihydrate) | Oral | Esomeprazole Apotex Esomeprazole GH Esomeprazole GxP Esomeprazole RBX Esomeprazole SZ Esomeprazole Sandoz Nexazole Nexium Nexole Pharmacor Esomeprazole |
| Esomeprazole and clarithromycin and amoxicillin | GRP-20639 | Pack containing 14 tablets (enteric coated) containing esomeprazole 20 mg (as magnesium), 14 tablets clarithromycin 500 mg and 28 capsules amoxicillin 500 mg (as trihydrate) | Oral | ESOMEPRAZOLE SANDOZ Hp7 |
|  |  | Pack containing 14 tablets (enteric coated) containing esomeprazole 20 mg (as magnesium trihydrate), 14 tablets clarithromycin 500 mg and 28 capsules amoxicillin 500 mg (as trihydrate) | Oral | Nexium Hp7 |
| Etanercept | GRP-21357 | Injections 50 mg in 1 mL single use pre-filled syringes, 4 | Injection | Brenzys Enbrel |
|  | GRP-21359 | Injection 50 mg in 1 mL single use auto-injector, 4 | Injection | Brenzys Enbrel |
| Everolimus | GRP-22362 | Tablet 5 mg | Oral | Afinitor Everolimus Sandoz |
|  | GRP-22363 | Tablet 10 mg | Oral | Afinitor Everolimus Sandoz |
| Fentanyl | GRP-15510 | Transdermal patch 7.65 mg | Transdermal | Denpax |
|  |  | Transdermal patch 12.375 mg | Transdermal | Dutran 75 Fenpatch 75 |
|  |  | Transdermal patch 12.6 mg | Transdermal | APO-Fentanyl Durogesic 75 Fentanyl Sandoz |
|  | GRP-15577 | Transdermal patch 2.55 mg | Transdermal | Denpax |
|  |  | Transdermal patch 4.125 mg | Transdermal | Dutran 25 Fenpatch 25 |
|  |  | Transdermal patch 4.2 mg | Transdermal | APO-Fentanyl Durogesic 25 Fentanyl Sandoz |
|  | GRP-15659 | Transdermal patch 5.10 mg | Transdermal | Denpax |
|  |  | Transdermal patch 8.25 mg | Transdermal | Dutran 50 Fenpatch 50 |
|  |  | Transdermal patch 8.4 mg | Transdermal | APO-Fentanyl Durogesic 50 Fentanyl Sandoz |
|  | GRP-15747 | Transdermal patch 10.20 mg | Transdermal | Denpax |
|  |  | Transdermal patch 16.5 mg | Transdermal | Dutran 100 Fenpatch 100 |
|  |  | Transdermal patch 16.8 mg | Transdermal | APO-Fentanyl Durogesic 100 Fentanyl Sandoz |
|  | GRP-15898 | Transdermal patch 1.28 mg | Transdermal | Denpax |
|  |  | Transdermal patch 2.063 mg | Transdermal | Dutran 12 Fenpatch 12 |
|  |  | Transdermal patch 2.1 mg | Transdermal | APO-Fentanyl Durogesic 12 Fentanyl Sandoz |
| Filgrastim | GRP-23379 | Injection 300 micrograms in 0.5 mL single-use pre-filled syringe | Injection | Neupogen Nivestim Zarzio |
|  |  | Injection 300 micrograms in 1 mL | Injection | Neupogen |
|  | GRP-23385 | Injection 480 micrograms in 0.5 mL single-use pre-filled syringe | Injection | Neupogen Nivestim Zarzio |
|  |  | Injection 480 micrograms in 1.6 mL | Injection | Neupogen |
| Flucloxacillin | GRP-23238 | Capsule 250 mg (as sodium) | Oral | Medsurge |
|  |  | Capsule 250 mg (as sodium monohydrate) | Oral | APO-Flucloxacillin Flopen Staphylex 250 |
|  | GRP-23239 | Capsule 500 mg (as sodium) | Oral | Medsurge |
|  |  | Capsule 500 mg (as sodium monohydrate) | Oral | APO-Flucloxacillin Flopen Staphylex 500 |
| Hydroxocobalamin | GRP-17689 | Injection 1 mg (as acetate) in 1 mL | Injection | Cobal-B12 Vita-B12 |
|  |  | Injection 1 mg (as chloride) in 1 mL | Injection | Hydroxo-B12 Neo-B12 |
| Imatinib | GRP-21074 | Capsule 100 mg (as mesilate) | Oral | CIPLA IMATINIB ADULT IMATINIB-DRLA Imatinib GH Imatinib-APOTEX |
|  |  | Tablet 100 mg (as mesilate) | Oral | Gilmat Glivec IMATINIB RBX Imatinib-Teva |
|  | GRP-21076 | Capsule 100 mg (as mesilate) | Oral | CIPLA IMATINIB ADULT IMATINIB-DRLA Imatinib GH Imatinib-APOTEX |
|  |  | Tablet 100 mg (as mesilate) | Oral | Glivec IMATINIB RBX |
|  | GRP-21079 | Capsule 400 mg (as mesilate) | Oral | CIPLA IMATINIB ADULT IMATINIB-DRLA Imatinib GH Imatinib-APOTEX |
|  |  | Tablet 400 mg (as mesilate) | Oral | Gilmat Glivec IMATINIB RBX Imatinib-Teva |
|  | GRP-21080 | Capsule 400 mg (as mesilate) | Oral | CIPLA IMATINIB ADULT IMATINIB-DRLA Imatinib GH Imatinib-APOTEX |
|  |  | Tablet 400 mg (as mesilate) | Oral | Glivec IMATINIB RBX |
| Imiquimod | GRP-17129 | Cream 50 mg per g, 2 g, 2 | Application | Aldara Pump |
|  |  | Cream 50 mg per g, 250 mg single use sachets, 12 | Application | APO-Imiquimod Aldara Aldiq |
| Infliximab | GRP-20382 | Powder for I.V. infusion 100 mg | Injection | Inflectra Remicade Renflexis |
|  | GRP-22461 | Powder for I.V. infusion 100 mg | Injection | Inflectra Renflexis |
| Lansoprazole | GRP-14641 | Capsule 30 mg | Oral | APO-Lansoprazole Lanzopran Zopral |
|  |  | Tablet 30 mg (orally disintegrating) | Oral | APO-Lansoprazole ODT Lansoprazole ODT GH Zopral ODT Zoton FasTabs |
| Levodopa with carbidopa | GRP-22957 | Tablet (modified release) 200 mg-50 mg (as monohydrate) | Oral | Sinemet CR |
|  |  | Tablet (prolonged release) 200 mg-50 mg | Oral | Sinemet CR Prolonged-Release Tablets |
| Meloxicam | GRP-15468 | Capsule 15 mg | Oral | APO-Meloxicam Chem mart Meloxicam MELOBIC Meloxicam Sandoz Mobic Movalis 15 Moxicam Terry White Chemists Meloxicam |
|  |  | Tablet 15 mg | Oral | APO-Meloxicam Chem mart Meloxicam 15 mg CIPLA MELOXICAM 15 MELOBIC Meloxiauro 15 Meloxibell Meloxicam AN Meloxicam Sandoz Meloxicam-GA Mobic Movalis 15 Moxicam 15 Pharmacor Meloxicam 15 Terry White Chemists Meloxicam 15 mg |
|  | GRP-15658 | Capsule 7.5 mg | Oral | APO-Meloxicam Chem mart Meloxicam MELOBIC Meloxicam Sandoz Mobic Movalis 7.5 Moxicam Terry White Chemists Meloxicam |
|  |  | Tablet 7.5 mg | Oral | APO-Meloxicam Chem mart Meloxicam 7.5 mg CIPLA MELOXICAM 7.5 MELOBIC Meloxiauro 7.5 Meloxibell Meloxicam AN Meloxicam Sandoz Meloxicam-GA Mobic Movalis 7.5 Moxicam 7.5 Pharmacor Meloxicam 7.5 Terry White Chemists Meloxicam 7.5 mg |
| Methotrexate | GRP-22721 | Injection 10 mg in 0.2 mL pre-filled syringe | Injection | Trexject |
|  |  | Injection 10 mg in 0.4 mL pre-filled syringe | Injection | Methoblastin PFS |
|  | GRP-22724 | Injection 20 mg in 0.4 mL pre-filled syringe | Injection | Trexject |
|  |  | injection 20 mg in 0.8 mL pre-filled syringe | Injection | Methoblastin PFS |
|  | GRP-22727 | Injection 15 mg in 0.3 mL pre-filled syringe | Injection | Trexject |
|  |  | Injection 15 mg in 0.6 mL pre-filled syringe | Injection | Methoblastin PFS |
|  | GRP-22728 | Injection 7.5 mg in 0.15 mL pre-filled syringe | Injection | Trexject |
|  |  | Injection 7.5 mg in 0.3 mL pre-filled syringe | Injection | Methoblastin PFS |
|  | GRP-22732 | Injection 25 mg in 0.5 mL pre-filled syringe | Injection | Trexject |
|  |  | Injection 25 mg in 1 mL pre-filled syringe | Injection | Methoblastin PFS |
| Methylprednisolone | GRP-15597 | Powder for injection 40 mg (as sodium succinate) | Injection | Methylpred |
|  |  | Powder for injection 40 mg (as sodium succinate) with diluent | Injection | Solu-Medrol |
| Morphine | GRP-20890 | Injection containing morphine hydrochloride trihydrate 10 mg in 1 mL | Injection | Morphine Juno |
|  |  | Injection containing morphine sulfate pentahydrate 10 mg in 1 mL | Injection | Hospira Pty Limited MORPHINE SULFATE 10 mg/1 mL MEDSURGE |
| Olanzapine | GRP-15643 | Tablet 20 mg (orally disintegrating) | Oral | APO-Olanzapine ODT Olanzapine AN ODT Olanzapine Sandoz ODT 20 PRYZEX ODT |
|  |  | Wafer 20 mg | Oral | Zypine ODT Zyprexa Zydis |
|  | GRP-15723 | Tablet 10 mg (orally disintegrating) | Oral | APO-Olanzapine ODT Olanzapine AN ODT Olanzapine ODT generichealth 10 Olanzapine Sandoz ODT 10 PRYZEX ODT |
|  |  | Wafer 10 mg | Oral | Zypine ODT Zyprexa Zydis |
|  | GRP-15797 | Tablet 5 mg (orally disintegrating) | Oral | APO-Olanzapine ODT Olanzapine AN ODT Olanzapine ODT generichealth 5 Olanzapine Sandoz ODT 5 PRYZEX ODT |
|  |  | Wafer 5 mg | Oral | Zypine ODT Zyprexa Zydis |
|  | GRP-15953 | Tablet 15 mg (orally disintegrating) | Oral | APO-Olanzapine ODT Olanzapine AN ODT Olanzapine Sandoz ODT 15 PRYZEX ODT |
|  |  | Wafer 15 mg | Oral | Zypine ODT Zyprexa Zydis |
| Omeprazole | GRP-14650 | Capsule 20 mg | Oral | APO-Omeprazole Maxor Omeprazole Sandoz Pemzo Pharmacor Omeprazole 20 Probitor |
|  |  | Tablet 20 mg | Oral | APO-Omeprazole Omeprazole AN Omeprazole generichealth Ozmep Pharmacor Omeprazole |
|  |  | Tablet 20 mg (as magnesium) | Oral | Acimax Tablets Losec Tablets Omepral Omeprazole Sandoz |
| Ondansetron | GRP-15402 | Tablet (orally disintegrating) 8 mg | Oral | APO-Ondansetron ODTOndansetron AN ODT Ondansetron Mylan ODT Ondansetron ODT GH Ondansetron ODT-DRLA Ondansetron SZ ODT Zilfojim ODT 8 |
|  |  | Wafer 8 mg | Oral | Zofran Zydis |
|  | GRP-15983 | Tablet (orally disintegrating) 4 mg | Oral | APO-Ondansetron ODTOndansetron AN ODT Ondansetron Mylan ODT Ondansetron ODT GH Ondansetron ODT-DRLA Ondansetron SZ ODT Zilfojim ODT 4 |
|  |  | Wafer 4 mg | Oral | Zofran Zydis |
|  | GRP-16933 | Tablet (orally disintegrating) 4 mg | Oral | APO-Ondansetron ODT Ondansetron AN ODT Ondansetron Mylan ODT Ondansetron ODT GH Ondansetron ODT-DRLA Ondansetron SZ ODT |
|  |  | Wafer 4 mg | Oral | Zofran Zydis |
|  | GRP-17042 | Tablet (orally disintegrating) 8 mg | Oral | APO-Ondansetron ODT Ondansetron AN ODT Ondansetron Mylan ODT Ondansetron ODT GH Ondansetron ODT-DRLA Ondansetron SZ ODT |
|  |  | Wafer 8 mg | Oral | Zofran Zydis |
| Perindopril | GRP-15442 | Tablet containing perindopril erbumine 4 mg | Oral | APO-Perindopril Blooms the Chemist Perindopril BTC Perindopril Chem mart Perindopril Idaprex 4 Indosyl Mono 4 Perindo Perindopril Actavis 4 Perindopril AN Perindopril APOTEX Perindopril generichealth Terry White Chemists Perindopril |
|  |  | Tablet containing perindopril arginine 5 mg | Oral | APO-Perindopril Arginine Coversyl 5mg PREXUM 5 |
|  | GRP-15525 | Tablet containing perindopril erbumine 8 mg | Oral | APO-Perindopril Blooms the Chemist Perindopril BTC Perindopril Chem mart Perindopril Idaprex 8 Indosyl Mono 8 Perindo Perindopril Actavis 8 Perindopril AN Perindopril APOTEX Perindopril generichealth Terry White Chemists Perindopril |
|  |  | Tablet containing perindopril arginine 10 mg | Oral | APO-Perindopril Arginine Coversyl 10mg PREXUM 10 |
|  | GRP-15965 | Tablet containing perindopril erbumine 2 mg | Oral | APO-Perindopril Blooms the Chemist Perindopril BTC Perindopril Chem mart Perindopril Idaprex 2 Indosyl Mono 2 Perindo Perindopril Actavis 2 Perindopril AN Perindopril APOTEX Terry White Chemists Perindopril |
|  |  | Tablet containing perindopril arginine 2.5 mg | Oral | APO-Perindopril Arginine Coversyl 2.5mg PREXUM 2.5 |
| Perindopril with indapamide | GRP-15765 | Tablet containing perindopril erbumine 4 mg with indapamide hemihydrate 1.25 mg | Oral | GenRx Perindopril/ Indapamide 4/1.25 Idaprex Combi 4/1.25 Indosyl Combi 4/1.25 Perindo Combi 4/1.25 Perindopril Combi Actavis 4/1.25 Perindopril and Indapamide AN 4/1.25 Perindopril/ Indapamide GH 4/1.25 |
|  |  | Tablet containing perindopril arginine 5 mg with indapamide hemihydrate 1.25 mg | Oral | Coversyl Plus 5mg/1.25mg Prexum Combi 5/1.25 |
| Ramipril | GRP-15424 | Capsule 5 mg | Oral | APO-Ramipril Tryzan Caps 5 |
|  |  | Tablet 5 mg | Oral | APO-Ramipril Prilace Ramace 5 mg Ramipril AN Ramipril Sandoz Ramipril Winthrop Tritace 5 mg Tryzan Tabs 5 |
|  | GRP-15431 | Capsule 10 mg | Oral | APO-Ramipril Prilace Ramace 10 mg Ramipril AN Ramipril Sandoz Ramipril Winthrop Tritace 10 mg Tryzan Caps 10 |
|  |  | Tablet 10 mg | Oral | APO-Ramipril Ramipril AN Ramipril Sandoz Tritace Tryzan Tabs 10 |
|  | GRP-15640 | Capsule 1.25 mg | Oral | APO-Ramipril Tryzan Caps 1.25 |
|  |  | Tablet 1.25 mg | Oral | Prilace Ramace 1.25 mg Ramipril Sandoz Ramipril Winthrop Tritace 1.25 mg Tryzan Tabs 1.25 |
|  | GRP-15769 | Capsule 2.5 mg | Oral | APO-Ramipril Tryzan Caps 2.5 |
|  |  | Tablet 2.5 mg | Oral | APO-Ramipril Prilace Ramace 2.5 mg Ramipril AN Ramipril Sandoz Ramipril Winthrop Tritace 2.5 mg Tryzan Tabs 2.5 |
| Ranibizumab | GRP-17312 | Solution for intravitreal injection 1.65 mg in 0.165 mL pre-filled syringe | Injection | Lucentis |
|  |  | Solution for intravitreal injection 2.3 mg in 0.23 mL | Injection | Lucentis |
| Rizatriptan | GRP-17623 | Tablet (orally disintegrating) 10 mg (as benzoate) | Oral | APO-Rizatriptan RIXALT Rizatriptan AN ODT Rizatriptan ODT APOTEX Rizatriptan ODT GH |
|  |  | Wafer 10 mg (as benzoate) | Oral | Maxalt Rizatriptan Wafers-10mg |
| Salbutamol | GRP-21361 | Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 20 | Inhalation | Ventolin Nebules |
|  |  | Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 30 | Inhalation | APO-Salbutamol Asmol 5 uni-dose Salbutamol AN Salbutamol Actavis Salbutamol Cipla |
|  | GRP-21535 | Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 20 | Inhalation | Ventolin Nebules |
|  |  | Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 30 | Inhalation | APO-Salbutamol Asmol 2.5 uni-dose Salbutamol AN Salbutamol Actavis Salbutamol Cipla |
| Sevelamer | GRP-23578 | Tablet containing sevelamer carbonate 800 mg | Oral | Sevelamer Apotex Sevelamer Lupin |
|  |  | Tablet containing sevelamer hydrochloride 800 mg | Oral | Renagel |
| Sumatriptan | GRP-15928 | Tablet (fast disintegrating) 50 mg (as succinate) | Oral | Imigran FDT |
|  |  | Tablet 50 mg (as succinate) | Oral | APO-Sumatriptan Imigran Iptam Pharmacor Sumatriptan 50 Sumatran Sumatriptan AN Sumatriptan Sandoz Sumatriptan generichealth |
| Tenofovir | GRP-21636 | Tablet containing tenofovir disoproxil phosphate 291 mg | Oral | Tenofovir GH |
|  |  | Tablet containing tenofovir disoproxil fumarate 300 mg | Oral | Tenofovir APOTEX Viread |
|  |  | Tablet containing tenofovir disoproxil maleate 300 mg | Oral | Tenofovir Disoproxil Mylan |
| Tenofovir with emtricitabine | GRP-21638 | Tablet containing tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg | Oral | Tenofovir EMT GH |
|  |  | Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg | Oral | Tenofovir/Emtricitabine 300/200 APOTEX |
|  |  | Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg | Oral | Tenofovir Disoproxil Emtricitabine Mylan 300/200 |
| Tenofovir with emtricitabine and efavirenz | GRP-23241 | Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and efavirenz 600 mg | Oral | Atripla |
|  |  | Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg and efavirenz 600 mg | Oral | Tenofovir Disoproxil/Emtricitabine/Efavirenz Mylan 300/200/600 |
| Tiotropium | GRP-23704 | Capsule containing powder for oral inhalation 13 micrograms (as bromide) (for use in Zonda device) | Inhalation by mouth | Braltus |
|  |  | Capsule containing powder for oral inhalation 18 micrograms (as bromide monohydrate) (for use in HandiHaler) | Inhalation by mouth | Spiriva |
| Zoledronic acid | GRP-17614 | Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL | Injection | APO-Zoledronic Acid DBL Zoledronic Acid DEZTRON Zometa |
|  |  | Solution for I.V. infusion 4 mg (as monohydrate) in 100 mL | Injection | DBL Zoledronic Acid |

Schedule 6—Pharmaceutical items with modified prescription circumstances during COVID‑19 pandemic

Note: See section 10A.

|  |  |  |
| --- | --- | --- |
| Pharmaceutical items with modified prescription circumstances during COVID-19 pandemic | | |
| Listed drug | Form | Manner of administration |
| Abatacept | Injection 125 mg in 1 mL single dose autoinjector | Injection |
| Abatacept | Injection 125 mg in 1 mL single dose pre‑filled syringe | Injection |
| Abatacept | Powder for I.V. infusion 250 mg | Injection |
| Adalimumab | Injection 20 mg in 0.4 mL pre‑filled syringe | Injection |
| Adalimumab | Injection 40 mg in 0.8 mL pre‑filled syringe | Injection |
| Adalimumab | Injection 40 mg in 0.8 mL pre‑filled syringe, 6 | Injection |
| Adalimumab | Injection 40 mg in 0.8 mL pre‑filled pen | Injection |
| Adalimumab | Injection 40 mg in 0.8 mL pre‑filled pen, 4 | Injection |
| Adalimumab | Injection 40 mg in 0.8 mL pre‑filled pen, 6 | Injection |
| Ambrisentan | Tablet 5 mg | Oral |
| Ambrisentan | Tablet 10 mg | Oral |
| Baricitinib | Tablet 2 mg | Oral |
| Baricitinib | Tablet 4 mg | Oral |
| Benralizumab | Injection 30 mg in 1 mL single dose pre‑filled syringe | Injection |
| Benralizumab | Injection 30 mg in 1 mL single dose pre‑filled pen | Injection |
| Bosentan | Tablet 62.5 mg (as monohydrate) | Oral |
| Bosentan | Tablet 125 mg (as monohydrate) | Oral |
| Certolizumab pegol | Injection 200 mg in 1 mL single use pre‑filled syringe | Injection |
| Certolizumab pegol | Solution for injection 200 mg in 1 mL pre‑filled pen | Injection |
| Dornase alfa | Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL | Inhalation |
| Epoprostenol | Powder for I.V. infusion 500 micrograms (as sodium) | Injection |
| Epoprostenol | Powder for I.V. infusion 500 micrograms (as sodium) with 2 vials diluent 50 mL | Injection |
| Epoprostenol | Powder for I.V. infusion 1.5 mg (as sodium) | Injection |
| Epoprostenol | Powder for I.V. infusion 1.5 mg (as sodium) with 2 vials diluent 50 mL | Injection |
| Etanercept | Injection set containing 4 vials powder for injection 25 mg and 4 pre‑filled syringes solvent 1 mL | Injection |
| Etanercept | Injection 50 mg in 1 mL single use auto‑injector, 4 | Injection |
| Etanercept | Injections 50 mg in 1 mL single use pre‑filled syringes, 4 | Injection |
| Golimumab | Injection 50 mg in 0.5 mL single use pre‑filled pen | Injection |
| Golimumab | Injection 50 mg in 0.5 mL single use pre‑filled syringe | Injection |
| Golimumab | Injection 100 mg in 1 mL single use pre‑filled pen | Injection |
| Guselkumab | Injection 100 mg in 1 mL single use pre‑filled syringe | Injection |
| Iloprost | Solution for inhalation 20 micrograms (as trometamol) in 2 mL | Inhalation |
| Infliximab | Powder for I.V. infusion 100 mg | Injection |
| Ivacaftor | Sachet containing granules 50 mg | Oral |
| Ivacaftor | Sachet containing granules 75 mg | Oral |
| Ivacaftor | Tablet 150 mg | Oral |
| Ixekizumab | Injection 80 mg in 1 mL single dose pre‑filled pen | Injection |
| Lenalidomide | Capsule 5 mg | Oral |
| Lenalidomide | Capsule 10 mg | Oral |
| Lenalidomide | Capsule 15 mg | Oral |
| Lenalidomide | Capsule 25 mg | Oral |
| Lumacaftor with ivacaftor | Sachet containing granules, lumacaftor 100 mg and ivacaftor 125 mg | Oral |
| Lumacaftor with ivacaftor | Sachet containing granules, lumacaftor 150 mg and ivacaftor 188 mg | Oral |
| Lumacaftor with ivacaftor | Tablet containing lumacaftor 100 mg with ivacaftor 125 mg | Oral |
| Lumacaftor with ivacaftor | Tablet containing lumacaftor 200 mg with ivacaftor 125 mg | Oral |
| Macitentan | Tablet 10 mg | Oral |
| Mannitol | Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers | Inhalation by mouth |
| Mepolizumab | Powder for injection 100 mg | Injection |
| Mepolizumab | Injection 100 mg in 1 mL single dose pre-filled pen | Injection |
| Montelukast | Tablet, chewable, 4 mg (as sodium) | Oral |
| Montelukast | Tablet, chewable, 5 mg (as sodium) | Oral |
| Nintedanib | Capsule 100 mg | Oral |
| Nintedanib | Capsule 150 mg | Oral |
| Omalizumab | Injection 75 mg in 0.5 mL single dose pre‑filled syringe | Injection |
| Omalizumab | Injection 150 mg in 1 mL single dose pre‑filled syringe | Injection |
| Pirfenidone | Capsule 267 mg | Oral |
| Pirfenidone | Tablet 267 mg | Oral |
| Pirfenidone | Tablet 801mg | Oral |
| Pomalidomide | Capsule 3 mg | Oral |
| Pomalidomide | Capsule 4 mg | Oral |
| Riociguat | Tablet 500 micrograms | Oral |
| Riociguat | Tablet 1 mg | Oral |
| Riociguat | Tablet 1.5 mg | Oral |
| Riociguat | Tablet 2 mg | Oral |
| Riociguat | Tablet 2.5 mg | Oral |
| Risankizumab | Injection 75 mg in 0.83 mL pre‑filled syringe | Injection |
| Rituximab | Solution for I.V. infusion 500 mg in 50 mL | Injection |
| Secukinumab | Injection 150 mg in 1 mL pre‑filled pen | Injection |
| Sildenafil | Tablet 20 mg (as citrate) | Oral |
| Somatropin | Injection 0.4 mg (1.2 i.u.) with diluent in single use syringe (without preservative) | Injection |
| Somatropin | Injection 0.6 mg (1.8 i.u.) with diluent in single use syringe (without preservative) | Injection |
| Somatropin | Injection 0.8 mg (2.4 i.u.) with diluent in single use syringe (without preservative) | Injection |
| Somatropin | Injection 1 mg (3 i.u.) with diluent in single use syringe (without preservative) | Injection |
| Somatropin | Injection 1.2 mg (3.6 i.u.) with diluent in single use syringe (without preservative) | Injection |
| Somatropin | Injection 1.4 mg (4.2 i.u.) with diluent in single use syringe (without preservative) | Injection |
| Somatropin | Injection 1.6 mg (4.8 i.u.) with diluent in single use syringe (without preservative) | Injection |
| Somatropin | Injection 1.8 mg (5.4 i.u.) with diluent in single use syringe (without preservative) | Injection |
| Somatropin | Injection 2 mg (6 i.u.) with diluent in single use syringe (without preservative) | Injection |
| Somatropin | Injection 4 mg (12 i.u.) vial with diluent (with preservative) | Injection |
| Somatropin | Injection 18 i.u. (6 mg) cartridge with 3.15 mL diluent (with preservative) | Injection |
| Somatropin | Injection 72 i.u. (24 mg) cartridge with 3.15 mL diluent (with preservative) | Injection |
| Somatropin | Powder for injection 5 mg (15 i.u.) with diluent in pre‑filled pen (with preservative) | Injection |
| Somatropin | Powder for injection 12 mg (36 i.u.) with diluent in pre‑filled pen (with preservative) | Injection |
| Somatropin | Injection 36 i.u. (12 mg) cartridge with 3.15 mL diluent (with preservative) | Injection |
| Somatropin | Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative) in pre‑filled pen | Injection |
| Somatropin | Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative) | Injection |
| Somatropin | Solution for injection 6 mg (18 i.u.) in 1.03 mL cartridge (with preservative) | Injection |
| Somatropin | Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative) | Injection |
| Somatropin | Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative) in pre‑filled pen | Injection |
| Somatropin | Solution for injection 10 mg (30 i.u.) in 2 mL cartridge (with preservative) | Injection |
| Somatropin | Solution for injection 12 mg (36 i.u.) in 1.5 mL cartridge (with preservative) | Injection |
| Somatropin | Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative) | Injection |
| Somatropin | Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative) in pre‑filled pen | Injection |
| Somatropin | Solution for injection 20 mg (60 i.u.) in 2.5 mL cartridge (with preservative) | Injection |
| Tadalafil | Tablet 20 mg | Oral |
| Tezacaftor with ivacaftor and ivacaftor | Pack containing 28 tablets tezacaftor 100 mg with ivacaftor 150 mg and 28 tablets ivacaftor 150 mg | Oral |
| Tildrakizumab | Injection 100 mg in 1 mL single dose pre‑filled syringe | Injection |
| Tocilizumab | Concentrate for injection 80 mg in 4 mL | Injection |
| Tocilizumab | Concentrate for injection 200 mg in 10 mL | Injection |
| Tocilizumab | Concentrate for injection 400 mg in 20 mL | Injection |
| Tocilizumab | Injection 162 mg in 0.9 mL single use pre‑filled pen | Injection |
| Tocilizumab | Injection 162 mg in 0.9 mL single use pre‑filled syringe | Injection |
| Tofacitinib | Tablet 5 mg | Oral |
| Ustekinumab | Injection 45 mg in 0.5 mL | Injection |
| Ustekinumab | Solution for I.V. infusion 130 mg in 26 mL | Injection |
| Vedolizumab | Powder for injection 300 mg | Injection |

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

**Abbreviation key—Endnote 2**

The abbreviation key sets out abbreviations that may be used in the endnotes.

**Legislation history and amendment history—Endnotes 3 and 4**

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

**Editorial changes**

The *Legislation Act 2003* authorises First Parliamentary Counsel to make editorial and presentational changes to a compiled law in preparing a compilation of the law for registration. The changes must not change the effect of the law. Editorial changes take effect from the compilation registration date.

If the compilation includes editorial changes, the endnotes include a brief outline of the changes in general terms. Full details of any changes can be obtained from the Office of Parliamentary Counsel.

**Misdescribed amendments**

A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation “(md)” added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation “(md not incorp)” is added to the details of the amendment included in the amendment history.

Endnote 2—Abbreviation key

|  |  |
| --- | --- |
| ad = added or inserted | o = order(s) |
| am = amended | Ord = Ordinance |
| amdt = amendment | orig = original |
| c = clause(s) | par = paragraph(s)/subparagraph(s) |
| C[x] = Compilation No. x | /sub‑subparagraph(s) |
| Ch = Chapter(s) | pres = present |
| def = definition(s) | prev = previous |
| Dict = Dictionary | (prev…) = previously |
| disallowed = disallowed by Parliament | Pt = Part(s) |
| Div = Division(s) | r = regulation(s)/rule(s) |
| ed = editorial change | reloc = relocated |
| exp = expires/expired or ceases/ceased to have | renum = renumbered |
| effect | rep = repealed |
| F = Federal Register of Legislation | rs = repealed and substituted |
| gaz = gazette | s = section(s)/subsection(s) |
| LA = *Legislation Act 2003* | Sch = Schedule(s) |
| LIA = *Legislative Instruments Act 2003* | Sdiv = Subdivision(s) |
| (md) = misdescribed amendment can be given | SLI = Select Legislative Instrument |
| effect | SR = Statutory Rules |
| (md not incorp) = misdescribed amendment | Sub‑Ch = Sub‑Chapter(s) |
| cannot be given effect | SubPt = Subpart(s) |
| mod = modified/modification | underlining = whole or part not |
| No. = Number(s) | commenced or to be commenced |

Endnote 3—Legislation history

| Name | Registration | Commencement | Application, saving and transitional provisions |
| --- | --- | --- | --- |
| PB 71 of 2012 | 28 Sept 2012 (F2012L01982) | 1 Oct 2012 (s 2) |  |
| PB 93 of 2012 | 29 Nov 2012 (F2012L02291) | 1 Dec 2012 (s 2) | — |
| PB 108 of 2012 | 18 Dec 2012 (F2012L02512) | 1 Jan 2013 (s 2) | — |
| PB 1 of 2013 | 10 Jan 2013 (F2013L00039) | 1 Feb 2013 (s 2) | — |
| PB 4 of 2013 | 21 Jan 2013 (F2013L00072) | 22 Jan 2013 (s 2) | — |
| PB 8 of 2013 | 14 Feb 2013 (F2013L00185) | 1 Mar 2013 (s 2) | — |
| PB 14 of 2013 | 27 Mar 2013 (F2013L00566) | 1 Apr 2013 (s 2) | — |
| PB 21 of 2013 | 24 Apr 2013 (F2013L00685) | 1 May 2013 (s 2) | — |
| PB 29 of 2013 | 24 May 2013 (F2013L00843) | 1 June 2013 (s 2) | — |
| PB 35 of 2013 | 5 June 2013 (F2013L00922) | 1 July 2013 (s 2) | — |
| PB 39 of 2013 | 21 June 2013 (F2013L01096) | 1 July 2013 (s 2) | — |
| PB 40 of 2013 | 29 July 2013 (F2013L01460) | 1 Aug 2013 (s 2) | — |
| PB 53 of 2013 | 16 Aug 2013 (F2013L01580) | 1 Sept 2013 (s 2) | — |
| PB 61 of 2013 | 10 Sept 2013 (F2013L01682) | 1 Oct 2013 (s 2) | — |
| PB 69 of 2013 | 4 Oct 2013 (F2013L01768) | 1 Nov 2013 (s 2) | — |
| PB 74 of 2013 | 29 Nov 2013 (F2013L02013) | 1 Dec 2013 (s 2) | — |
| PB 88 of 2013 | 20 Dec 2013 (F2013L02170) | 1 Jan 2014 (s 2) | — |
| PB 1 of 2014 | 10 Jan 2014 (F2014L00051) | 1 Feb 2014 (s 2) | — |
| PB 9 of 2014 | 17 Feb 2014 (F2014L00147) | 1 Mar 2014 (s 2) | — |
| PB 17 of 2014 | 26 Mar 2014 (F2014L00342) | 1 Apr 2014 (s 2) | — |
| PB 27 of 2014 | 11 Apr 2014 (F2014L00399) | 1 May 2014 (s 2) | — |
| PB 36 of 2014 | 21 May 2014 (F2014L00588) | 1 June 2014 (s 2) | — |
| PB 45 of 2014 | 20 June 2014 (F2014L00763) | 1 July 2014 (s 2) | — |
| PB 51 of 2014 | 1 July 2014 (F2014L00921) | 1 July 2014 (s 2) | — |
| PB 52 of 2014 | 31 July 2014 (F2014L01058) | 1 Aug 2014 (s 2) | — |
| PB 61 of 2014 | 25 Aug 2014 (F2014L01121) | 1 Sept 2014 (s 2) | — |
| PB 72 of 2014 | 30 Sept 2014 (F2014L01298) | 1 Oct 2014 (s 2) | — |
| PB 82 of 2014 | 24 Oct 2014 (F2014L01395) | 1 Nov 2014 (s 2) | — |
| PB 88 of 2014 | 28 Nov 2014 (F2014L01602) | 1 Dec 2014 (s 2) | — |
| PB 101 of 2014 | 22 Dec 2014 (F2014L01780) | 1 Jan 2015 (s 2) | — |
| PB 109 of 2014 | 23 Dec 2014 (F2014L01795) | 1 Jan 2015 (s 2) | — |
| PB 1 of 2015 | 14 Jan 2015 (F2015L00040) | 1 Feb 2015 (s 2) | — |
| PB 10 of 2015 | 25 Feb 2015 (F2015L00205) | 1 Mar 2015 (s 2) | — |
| PB 26 of 2015 | 26 Mar 2015 (F2015L00342) | 1 Apr 2015 (s 2) | — |
| PB 39 of 2015 | 24 Apr 2015 (F2015L00595) | 1 May 2015 (s 2) | — |
| PB 47 of 2015 | 29 May 2015 (F2015L00762) | 1 June 2015 (s 2) | — |
| PB 55 of 2015 | 30 June 2015 (F2015L01058) | 1 July 2015 (s 2) | — |
| PB 68 of 2015 | 31 July 2015 (F2015L01212) | 1 Aug 2015 (s 2) | — |
| PB 78 of 2015 | 28 Aug 2015 (F2015L01351) | 1 Sept 2015 (s 2) | — |
| PB 90 of 2015 | 29 Sept 2015 (F2015L01520) | 1 Oct 2015 (s 2) | — |
| PB 101 of 2015 | 27 Oct 2015 (F2015L01701) | 1 Nov 2015 (s 2) | — |
| PB 107 of 2015 | 30 Nov 2015 (F2015L01878) | 1 Dec 2015 (s 2) | — |
| PB 117 of 2015 | 24 Dec 2015 (F2015L02141) | 1 Jan 2016 (s 2) | — |
| PB 1 of 2016 | 1 Feb 2016 (F2016L00075) | 1 Feb 2016 (s 2) | — |
| PB 11 of 2016 | 23 Feb 2016 (F2016L00136) | 1 Mar 2016 (s 2) | — |
| PB 18 of 2016 | 1 Apr 2016 (F2016L00470) | 1 Apr 2016 (s 2) | — |
| PB 29 of 2016 | 29 Apr 2016 (F2016L00604) | 1 May 2016 (s 2) | — |
| PB 41 of 2016 | 30 May 2016 (F2016L00856) | 1 June 2016 (s 2) | — |
| PB 52 of 2016 | 22 June 2016 (F2016L01056) | 1 July 2016 (s 2) | — |
| PB 62 of 2016 | 19 July 2016 (F2016L01185) | 1 Aug 2016 (s 2) | — |
| PB 72 of 2016 | 18 Aug 2016 (F2016L01296) | 1 Sept 2016 (s 2) | — |
| PB 81 of 2016 | 30 Sept 2016 (F2016L01560) | 1 Oct 2016 (s 2) | — |
| PB 90 of 2016 | 31 Oct 2016 (F2016L01689) | 1 Nov 2016 (s 2) | — |
| PB 97 of 2016 | 30 Nov 2016 (F2016L01832) | 1 Dec 2016 (s 2) | — |
| PB 110 of 2016 | 22 Dec 2016 (F2016L02026) | 1 Jan 2017 (s 2) | — |
| PB 1 of 2017 | 25 Jan 2017 (F2017L00070) | 1 Feb 2017 (s 2) | — |
| PB 15 of 2017 | 30 Mar 2017 (F2017L00362) | 1 Apr 2017 (s 2) | — |
| PB 26 of 2017 | 28 Apr 2017 (F2017L00483) | 1 May 2017 (s 2) | — |
| PB 34 of 2017 | 31 May 2017 (F2017L00625) | 1 June 2017 (s 2) | — |
| PB 45 of 2017 | 29 June 2017 (F2017L00825) | 1 July 2017 (s 2) | — |
| PB 55 of 2017 | 25 July 2017 (F2017L00948) | 1 Aug 2017 (s 2) | — |
| PB 62 of 2017 | 29 Aug 2017 (F2017L01098) | 1 Sept 2017 (s 2) | — |
| PB 71 of 2017 | 26 Sept 2017 (F2017L01264) | 1 Oct 2017 (s 2) | — |
| PB 84 of 2017 | 23 Oct 2017 (F2017L01383) | 1 Nov 2017 (s 2) | — |
| PB 92 of 2017 | 29 Nov 2017 (F2017L01548) | 1 Dec 2017 (s 2) | — |
| PB 101 of 2017 | 18 Dec 2017 (F2017L01644) | 1 Jan 2018 (s 2) | — |
| PB 1 of 2018 | 24 Jan 2018 (F2018L00057) | 1 Feb 2018 (s 2) | — |
| PB 8 of 2018 | 20 Feb 2018 (F2018L00129) | 21 Feb 2018 (s 2) | — |
| PB 12 of 2018 | 28 Feb 2018 (F2018L00161) | 1 Mar 2018 (s 2) | — |
| PB 19 of 2018 | 28 Mar 2018 (F2018L00420) | 1 Apr 2018 (s 2) | — |
| PB 29 of 2018 | 27 Apr 2018 (F2018L00532) | 1 May 2018 (s 2) | — |
| PB 36 of 2018 | 31 May 2018 (F2018L00685) | 1 June 2018 (s 2) | — |
| PB 50 of 2018 | 29 June 2018 (F2018L00956) | 1 July 2018 (s 2) | — |
| PB 63 of 2018 | 31 July 2018 (F2018L01071) | 1 Aug 2018 (s 2) | — |
| PB 74 of 2018 | 30 Aug 2018 (F2018L01223) | 1 Sept 2018 (s 2) | — |
| PB 83 of 2018 | 27 Sept 2018 (F2018L01359) | 1 Oct 2018 (s 2) | — |
| PB 91 of 2018 | 29 Oct 2018 (F2018L01491) | 1 Nov 2018 (s 2) | — |
| PB 99 of 2018 | 29 Nov 2018 (F2018L01625) | 1 Dec 2018 (s 2) | — |
| PB 110 of 2018 | 19 Dec 2018 (F2018L01802) | 1 Jan 2019 (s 2) | — |
| PB 1 of 2019 | 31 Jan 2019 (F2019L00073) | 1 Feb 2019 (s 2) | — |
| PB 10 of 2019 | 27 Feb 2019 (F2019L00211) | 1 Mar 2019 (s 2) | — |
| PB 17 of 2019 | 29 Mar 2019 (F2019L00472) | 1 Apr 2019 (s 2) | — |
| PB 28 of 2019 | 30 Apr 2019 (F2019L00663) | 1 May 2019 (s 2) | — |
| PB 36 of 2019 | 31 May 2019 (F2019L00713) | 1 June 2019 (s 2) | — |
| PB 46 of 2019 | 28 June 2019 (F2019L00907) | 1 July 2019 (s 2) | — |
| PB 58 of 2019 | 30 July 2019 (F2019L01020) | 1 Aug 2019 (s 2) | — |
| PB 66 of 2019 | 30 Aug 2019 (F2019L01129) | 1 Sept 2019 (s 2) | — |
| PB 76 of 2019 | 30 Sept 2019 (F2019L01291) | 1 Oct 2019 (s 2) | — |
| PB 84 of 2019 | 31 Oct 2019 (F2019L01394) | 1 Nov 2019 (s 2) | — |
| PB 92 of 2019 | 28 Nov 2019 (F2019L01520) | 1 Dec 2019 (s 2) | — |
| PB 104 of 2019 | 23 Dec 2019 (F2019L01690) | 1 Jan 2020 (s 2) | — |
| PB 1 of 2020 | 30 Jan 2020 (F2020L00069) | 1 Feb 2020 (s 2) | — |
| PB 14 of 2020 | 28 Feb 2020 (F2020L00184) | 1 Mar 2020 (s 2) | — |
| PB 20 of 2020 | 31 Mar 2020 (F2020L00365) | 1 Apr 2020 (s 2) | — |
| PB 32 of 2020 | 30 Apr 2020 (F2020L00531) | 1 May 2020 (s 2(1) item 1) | — |
| PB 33 of 2020 | 30 Apr 2020 (F2020L00523) | 1 May 2020 (s 2) | — |
| PB 42 of 2020 | 29 May 2020 (F2020L00641) | 1 June 2020 (s 2) | — |
| PB 55 of 2020 | 29 June 2020 (F2020L00841) | 1 July 2020 (s 2) | — |

Endnote 4—Amendment history

| Provision affected | How affected |
| --- | --- |
| s 2 | rep LIA s 48D |
| s 3 | rep LIA s 48C |
| s 4 | am PB 93 of 2012; PB 26 and 55 of 2015; PB 11 of 2016; PB 83 of 2018 |
|  | ed C72 |
| s 9 | am PB 8 of 2018 |
| s 10 | am PB 32 of 2020 |
|  | (3A) rep 1 Oct 2020 (s 10A(3)) |
| s 10A | ad PB 32 of 2020 |
|  | rep 1 Oct 2020 (s 10A(3)) |
| s 11 | am PB 26 of 2015; PB 29 of 2016 |
| s 12 | am PB 26 of 2015; PB 29 of 2016 |
| s 13 | am PB 26 of 2015; PB 29 of 2016 |
| s 14 | am PB 26 of 2015 |
| **Schedule 1** |  |
| Schedule 1 | am PB 93 and 108 of 2012; PB 1, 4, 8, 14, 21, 29, 35, 39, 40, 53, 61, 69, 74 and 88 of 2013; PB 1, 9, 17, 27, 36, 45, 51, 52, 61, 72, 82, 88, 101 and 109 of 2014; PB 1, 10 and 26 of 2015; PB 39, 47, 55, 68 (Sch 1 par 9(e) md), 78, 90, 101, 107 and 117 of 2015; PB 1, 11, 18, 29, 41, 52, 62, 72, 81 (Sch 1 item 56 md), 90, 97 and 110 of 2016 |
|  | ed C51 |
|  | am PB 1 of 2017 |
|  | ed C53 |
|  | am PB 15 of 2017; PB 26 of 2017; PB 34 of 2017; PB 45 of 2017 (Sch 1 item 10 md incorp); PB 55 of 2017; PB 62 of 2017; PB 71 of 2017; PB 84 of 2017; PB 92 of 2017; PB 101 of 2017; PB 1 of 2018; PB 12 of 2018; PB 19 of 2018; PB 29 of 2018; PB 36 of 2018 |
|  | rs PB 50 of 2018 |
|  | am PB 63 of 2018; PB 74 of 2018; PB 83 of 2018 |
|  | ed C72 |
|  | am PB 91 of 2018; PB 99 of 2018; PB 110 of 2018; PB 1 of 2019 |
|  | ed C76 |
|  | am PB 10 of 2019; PB 17 of 2019; PB 28 of 2019 |
|  | ed C79 |
|  | am PB 36 of 2019; PB 46 of 2019; PB 58 of 2019; PB 66 of 2019 |
|  | ed C83 |
|  | am PB 76 of 2019 |
|  | ed C84 |
|  | am PB 84 of 2019; PB 92 of 2019; PB 104 of 2019; PB 1 of 2020; PB 14 of 2020; PB 20 of 2020; PB 33 of 2020; PB 42 of 2020; PB 55 of 2020 |
| **Schedule 2** |  |
| Schedule 2 | am PB 68 and 90 of 2015 |
| **Schedule 3** |  |
| Schedule 3 | am PB 93 and 108 of 2012; PB 1, 8, 14, 29, 40, 61, 74 and 88 of 2013; PB 1, 9, 17, 36, 45, 52, 61, 72, 82, 88 and 101 of 2014; PB 1, 10, 26, 39, 47, 55, 68, 78, 90, 101, 107 and 117 of 2015; PB 1, 11, 18, 41, 52, 62, 81, 97 and 110 of 2016; PB 1 of 2017; PB 15 of 2017; PB 26 of 2017; PB 34 of 2017; PB 45 of 2017; PB 84 of 2017; PB 92 of 2017; PB 101 of 2017; PB 12 of 2018; PB 19 of 2018; PB 29 of 2018; PB 36 of 2018; PB 63 of 2018; PB 74 of 2018; PB 83 of 2018; PB 91 of 2018; PB 99 of 2018; PB 110 of 2018; PB 1 of 2019; PB 10 of 2019; PB 17 of 2019; PB 28 of 2019; PB 36 of 2019; PB 46 of 2019; PB 58 of 2019 |
|  | ed C82 |
|  | am PB 66 of 2019; PB 76 of 2019; PB 84 of 2019; PB 92 of 2019; PB 104 of 2019; PB 14 of 2020; PB 20 of 2020; PB 55 of 2020 |
| **Schedule 4** |  |
| Schedule 4 | am PB 93 and 108 of 2012; PB 1, 8, 14, 21, 29, 35, 40, 53, 61, 69, 74 and 88 of 2013; PB 1, 9, 17, 27, 36, 45, 52, 61, 72, 82, 88 and 101 of 2014; PB 1, 10, 26, 39, 47, 55, 68, 78, 90, 101, 107 and 117 of 2015; PB 1, 11, 18, 29, 41, 52, 62, 72, 81, 90, 97 and 110 of 2016; PB 1 of 2017; PB 15 of 2017; PB 26 of 2017; PB 34 of 2017 (Sch 1 item 124 md not incorp); PB 45 of 2017; PB 55 of 2017; PB 62 of 2017; PB 71 of 2017; PB 84 of 2017; PB 92 of 2017; PB 101 of 2017; PB 1 of 2018; PB 12 of 2018; PB 19 of 2018; PB 29 of 2018; PB 36 of 2018; PB 50 of 2018; PB 63 of 2018; PB 74 of 2018; PB 83 of 2018; PB 91 of 2018; PB 99 of 2018; PB 110 of 2018; PB 1 of 2019; PB 10 of 2019; PB 17 of 2019; PB 28 of 2019; PB 36 of 2019 (Sch 1 par 50(a), (c), (g)–(i) md not incorp); PB 46 of 2019; PB 58 of 2019; PB 66 of 2019; PB 76 of 2019 |
|  | ed C84 |
|  | am PB 84 of 2019; PB 92 of 2019; PB 104 of 2019; PB 1 of 2020; PB 14 of 2020; PB 20 of 2020; PB 33 of 2020; PB 42 of 2020; PB 55 of 2020 |
| **Schedule 5** |  |
| Schedule 5 | ad PB 107, 2015 |
|  | am PB 1, 11, 18, 29, 41, 52, 62, 72, 81, 90 and 97 of 2016; PB 1 of 2017; PB 15 of 2017; PB 26 of 2017; PB 34 of 2017; PB 45 of 2017; PB 55 of 2017; PB 62 of 2017; PB 71 of 2017; PB 84 of 2017; PB 92 of 2017; PB 101 of 2017; PB 1 of 2018; PB 12 of 2018; PB 19 of 2018 (Sch 1 item 127 md not incorp); PB 29 of 2018; PB 36 of 2018 |
|  | rs PB 50 of 2018 |
|  | am PB 63 of 2018 (amdt never applied (Sch 1 item 134)); PB 74 of 2018; PB 83 of 2018; PB 91 of 2018; PB 99 of 2018; PB 110 of 2018; PB 1 of 2019; PB 10 of 2019; PB 17 of 2019; PB 28 of 2019 |
|  | ed C79 |
|  | am PB 46 of 2019; PB 58 of 2019; PB 66 of 2019; PB 76 of 2019; PB 84 of 2019; PB 92 of 2019; PB 104 of 2019; PB 1 of 2020; PB 14 of 2020 |
|  | ed C89 |
|  | am PB 20 of 2020; PB 42 of 2020; PB 55 of 2020 |
| **Schedule 6** |  |
| Schedule 6 | ad PB 32 of 2020 |
|  | am PB 42 of 2020 |
|  | rep 1 Oct 2020 (s 10A(3)) |