PB 82 of 2020

National Health (Highly specialised drugs program) Special Arrangement Amendment Instrument 2020 (No. 7)

National Health Act 1953

I, BEN SLADIC, Assistant Secretary, Pharmacy Branch, Technology Assessment and Access Division, Department of Health, delegate of the Minister for Health, make this Amendment Instrument under subsection 100(2) of the *National Health Act 1953*.

Dated 27 August 2020

BEN SLADIC
Assistant Secretary
Pharmacy Branch
Technology Assessment and Access Division
Department of Health

1 Name of Instrument

(1) This Instrument is the *National Health (Highly specialised drugs program) Special Arrangement Amendment Instrument 2020 (No. 7)*.

(2) This Instrument may also be cited as PB 82 of 2020.

2 Commencement

This Instrument commences on 1 September 2020.

3 Amendment of *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010)

Schedule 1 amends the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010).

Schedule 1 Amendments

[1] Schedule 1, entry for Adefovir

omit:

	Hepsera	GI	C4490 C4510	60	5	D

[2] Schedule 1, entry for Deferiprone in each of the forms: Tablet 500 mg; Tablet 1000 mg; and Oral solution 100 mg per mL, 250 mL

omit from the column headed "Responsible Person": **TX** *substitute:* **EU**

[3] Schedule 1, entry for Desferrioxamine in each of the forms: Powder for injection containing desferrioxamine mesilate 500 mg; and Powder for injection containing desferrioxamine mesilate 2 g

omit from the column headed "Brand": **Hospira Pty Limited** *substitute:* **DBL Desferrioxamine Mesilate**

[4] Schedule 2

omit from the column headed "Responsible Person" for the Code "EU": **Emerge Health Pty Ltd** *substitute:* **Chiesi Australia Pty Ltd**

[5] Schedule 3, entry for Abacavir

(a) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4454":* **Continuing treatment** *substitute:* **Continuing**

(b) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4512":* **Initial treatment** *substitute:* **Initial**

[6] Schedule 3, entry for Abacavir with Lamivudine

(a) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4527":* **Initial treatment** *substitute:* **Initial**

(b) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4528":* **Continuing treatment** *substitute:* **Continuing**

[7] Schedule 3, entry for Abacavir with Lamivudine and Zidovudine

(a) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4480":* **Continuing treatment** *substitute:* **Continuing**

(b) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4495":* **Initial treatment** *substitute:* **Initial**

[8] Schedule 3, entry for Adefovir

substitute:

Adefovir	C4490		Chronic hepatitis B infection Patient must not have cirrhosis; AND Patient must have failed antihepadnaviral therapy; AND Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.	Compliance with Authority Required procedures - Streamlined Authority Code 4490

	C4510		Chronic hepatitis B infection Patient must have cirrhosis; AND Patient must have failed antihepadnaviral therapy; AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 4510

[9] Schedule 3, entry for Atazanavir

(a) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4454":* **Continuing treatment** *substitute:* **Continuing**

(b) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4512":* **Initial treatment** *substitute:* **Initial**

[10] Schedule 3, entry for Clozapine

(a) *omit entry for Circumstances Code "C4998" and substitute:*

	C4998		Schizophrenia Continuing treatment Must be treated by a psychiatrist; OR Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist. Patient must have previously received PBS-subsidised therapy with this drug for this condition; AND Patient must have completed at least 18 weeks therapy; AND Patient must be on a clozapine dosage considered stable by a treating psychiatrist; AND The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals. A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.	Compliance with Authority Required procedures - Streamlined Authority Code 4998

(b) *omit entry for Circumstances Code "C5015" and substitute:*

	C5015		Schizophrenia Initial treatment Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient. Patient must be non-responsive to other neuroleptic agents; OR Patient must be intolerant of other neuroleptic agents. Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction. The name of the consulting psychiatrist should be included in the patient's medical records. A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.	Compliance with Authority Required procedures - Streamlined Authority Code 5015

[11] Schedule 3, entry for Dolutegravir

(a) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4454":* **Continuing treatment** *substitute:* **Continuing**

(b) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4512":* **Initial treatment** *substitute:* **Initial**

[12] Schedule 3, entry for Dornase alfa

omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C5635": **Treatment Phase:**

[13] Schedule 3, entry for Eculizumab

omit entry for Circumstances Code "C6642" and substitute:

	C6642	P6642	Atypical haemolytic uraemic syndrome (aHUS) Initial treatment - Balance of Supply Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist. Patient must have received PBS-subsidised initial supply of eculizumab for this condition; AND Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample; AND Patient must not receive more than 20 weeks supply under this restriction. ADAMTS-13 activity result must have been submitted to the Department of Human Services. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial Treatment, ADAMTS-13 activity must have been measured 1-2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.	Compliance with Written Authority Required procedures

[14] Schedule 3, entry for Efavirenz

(a) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4454":* **Continuing treatment** *substitute:* **Continuing**

(b) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4512":* **Initial treatment** *substitute:* **Initial**

[15] Schedule 3, entry for Everolimus

(a) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C5554":* **Treatment Phase:**

(b) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C5795":* **Treatment Phase:**

[16] Schedule 3, entry for Fosamprenavir

(a) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4454":* **Continuing treatment** *substitute:* **Continuing**

(b) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4512":* **Initial treatment** *substitute:* **Initial**

[17] Schedule 3, entry for Interferon alfa-2a

omit entry for Circumstances Code "C5042" and substitute:

	C5042		Chronic Myeloid Leukaemia (CML) The condition must be Philadelphia chromosome positive.	Compliance with Authority Required procedures - Streamlined Authority Code 5042

[18] Schedule 3, entry for Lamivudine

(a) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4454":* **Continuing treatment** *substitute:* **Continuing**

(b) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4512":* **Initial treatment** *substitute:* **Initial**

[19] Schedule 3, entry for Lamivudine with zidovudine

(a) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4454":* **Continuing treatment** *substitute:* **Continuing**

(b) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4512":* **Initial treatment** *substitute:* **Initial**

[20] Schedule 3, entry for Lanthanum

omit entry for Circumstances Code "C5530" and substitute:

	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

[21] Schedule 3, entry for Lenalidomide

(a) *omit entry for Circumstances Code "C4282" and substitute:*

	C4282		Myelodysplastic syndrome Continuing treatment Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS); AND Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities; AND Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome; AND Patient must have achieved and maintained transfusion independence; or least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide; AND Patient must not have progressive disease. Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program. The first authority application for continuing supply must be made in writing. Subsequent authority applications for continuing supply may be made by telephone. The following evidence of response must be provided at each application: (i) a haemoglobin level taken within the last 4 weeks; and (ii) the date of the last transfusion; and (iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; and (iv) a statement confirming that the patient has not progressed to acute myeloid leukaemia.	Compliance with Written Authority Required procedures

(b) *omit entry for Circumstances Code "C4287" and substitute:*

	C4287		Myelodysplastic syndrome Initial treatment The treatment must be limited to a maximum duration of 16 weeks; AND Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS); AND Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities; AND Patient must be red blood cell transfusion dependent. Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias. Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations: 1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR 2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR 3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR 4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR 5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR 6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR 7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias. Classification of a patient as red blood cell transfusion dependent requires that: (i) the patient has been transfused within the last 8 weeks; and (ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment. Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Myelodysplastic Syndrome Lenalidomide Authority Application - Supporting Information Form; and (c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and (d) a copy of the full blood examination report; and (e) a copy of the pathology report detailing the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and (f) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red cell units transfused in the 4 and 6 months preceding the date of this application; and (g) a signed patient acknowledgement form.	Compliance with Written Authority Required procedures

(c) *omit entry for Circumstances Code "C10335" and substitute:*

	C10335		Multiple myeloma Continuing treatment with lenalidomide monotherapy following initial treatment with lenalidomide therapy in newly diagnosed disease Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have demonstrated progressive disease; AND The treatment must be as monotherapy. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.	Compliance with Authority Required procedures

[22] Schedule 3, entry for Lopinavir with ritonavir

(a) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4454":* **Continuing treatment** *substitute:* **Continuing**

(b) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4512":* **Initial treatment** *substitute:* **Initial**

[23] Schedule 3, entry for Mycophenolic Acid

(a) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C5554":* **Treatment Phase:**

(b) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C5600":* **Treatment Phase:**

(c) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C5653":* **Treatment Phase:**

(d) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C5795":* **Treatment Phase:**

[24] Schedule 3, entry for Nevirapine

(a) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4454":* **Continuing treatment** *substitute:* **Continuing**

(b) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4512":* **Initial treatment** *substitute:* **Initial**

(c) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4526":* **Initial treatment** *substitute:* **Initial**

[25] Schedule 3, entry for Octreotide

(a) *omit entry for Circumstances Code "C9232" and substitute:*

	C9232		Vasoactive intestinal peptide secreting tumour (VIPoma) The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 9232

(b) *omit entry for Circumstances Code "C9233" and substitute:*

	C9233		Acromegaly The condition must be active; AND Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND The treatment must be after failure of other therapy including dopamine agonists; OR The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks; AND The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily; AND The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	Compliance with Authority Required procedures - Streamlined Authority Code 9233

(c) *omit entry for Circumstances Code "C9262" and substitute:*

	C9262		Acromegaly The condition must be controlled with octreotide immediate release injections; AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND The treatment must cease if IGF1 is not lower after 3 months of treatment; AND The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	Compliance with Authority Required procedures - Streamlined Authority Code 9262

(d) *omit entry for Circumstances Code "C9288" and substitute:*

	C9288		Vasoactive intestinal peptide secreting tumour (VIPoma) Patient must have achieved symptom control on octreotide immediate release injections; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 9288

(e) *omit entry for Circumstances Code "C9289" and substitute:*

	C9289		Functional carcinoid tumour The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 9289

(f) *omit entry for Circumstances Code "C9313" and substitute:*

	C9313		Functional carcinoid tumour Patient must have achieved symptom control on octreotide immediate release injections; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 9313

[26] Schedule 3, entry for Peginterferon alfa-2a

omit entry for Circumstances Code "C5004" and substitute:

	C5004		Chronic hepatitis C infection Must be treated in an accredited treatment centre. Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age. Patient must have compensated liver disease; AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND Patient must have a contraindication to ribavirin; AND The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND The treatment must be limited to a maximum duration of 48 weeks.	Compliance with Authority Required procedures - Streamlined Authority Code 5004

			Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.	

[27] Schedule 3, entry for Raltegravir

(a) *omit entry for Circumstances Code "C4274" and substitute:*

	C4274		HIV infection Continuing The treatment must be in combination with other antiretroviral agents; AND Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy; AND Patient must have previously received PBS-subsidised therapy for HIV infection. Patient must be aged 2 years or older.	Compliance with Authority Required procedures - Streamlined Authority Code 4274

(b) *omit entry for Circumstances Code "C4275" and substitute:*

	C4275		HIV infection Initial The treatment must be in combination with other antiretroviral agents; AND Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy; AND Patient must have a CD4 count of less than 500 per cubic millimetre; OR Patient must have symptomatic HIV disease. Patient must be aged 2 years or older.	Compliance with Authority Required procedures - Streamlined Authority Code 4275

(c) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4454":* **Continuing treatment** *substitute:* **Continuing**

(d) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4512":* **Initial treatment** *substitute:* **Initial**

[28] Schedule 3, entry for Rilpivirine

(a) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4454":* **Continuing treatment** *substitute:* **Continuing**

(b) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4512":* **Initial treatment** *substitute:* **Initial**

[29] Schedule 3, entry for Riociguat

(a) *omit entry for Circumstances Code "C6645" and substitute:*

	C6645		Chronic thromboembolic pulmonary hypertension (CTEPH) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must demonstrate stable or responding disease; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated in a centre with expertise in the management of CTEPH. Patient must be aged 18 years or older. Applications for authorisation must be in writing and must include:(1) a completed authority prescription form; and(2) a completed CTEPH PBS Continuing Authority Application - Supporting Information form which includes results from the three tests below, where available:(i) RHC composite assessment; and(ii) ECHO composite assessment; and(iii) 6 Minute Walk Test (6MWT).	Compliance with Written Authority Required procedures

			Test requirements to establish response to treatment for continuation of treatment are as follows: The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments plus 6MWT; (2) RHC plus ECHO composite assessments; (3) RHC composite assessment plus 6MWT; (4) ECHO composite assessment plus 6MWT; (5) RHC composite assessment only; (6) ECHO composite assessment only. The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application. Response to this drug is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease. The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment. A maximum of 5 repeats will be authorised. Applications for continuing treatment with this drug should be made two weeks prior to the completion of the 6-month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician. Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.	

(b) *omit entry for Circumstances Code "C6664" and substitute:*

	C6664		Chronic thromboembolic pulmonary hypertension (CTEPH) Initial treatment Patient must have WHO Functional Class II, III or IV CTEPH; AND The condition must be inoperable by pulmonary endarterectomy; OR The condition must be recurrent or persistent following pulmonary endarterectomy; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated in a centre with expertise in the management of CTEPH. Patient must be aged 18 years or older. CTEPH that is inoperable by pulmonary endarterectomy is defined as follows: Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm^{-5}measured at least 90 days after start of full anticoagulation; and	Compliance with Written Authority Required procedures

			A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation. CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows: RHC demonstrating a PVR of greater than 300 dyn*sec*cm^{-5}measured at least 180 days following pulmonary endarterectomy. Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application. Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available: (i) RHC composite assessment, and (ii) ECHO composite assessment, and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgment form; and (4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or (5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or (6) confirmation of an echocardiogram demonstrating right ventricular dysfunction. Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions. Approvals for subsequent authority prescription will be limited to 1 month of treatment, The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats. The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.	

[30] Schedule 3, entry for Ritonavir

(a) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4454":* **Continuing treatment** *substitute:* **Continuing**

(b) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4512":* **Initial treatment** *substitute:* **Initial**

[31] Schedule 3, entry for Saquinavir

(a) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4454":* **Continuing treatment** *substitute:* **Continuing**

(b) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4512":* **Initial treatment** *substitute:* **Initial**

[32] Schedule 3, entry for Sevelamer

omit entry for Circumstances Code "C5530" and substitute:

	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

[33] Schedule 3, entry for Sirolimus

omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C5795": **Treatment Phase:**

[34] Schedule 3, entry for Sucroferric oxyhydroxide

omit entry for Circumstances Code "C5530" and substitute:

	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

[35] Schedule 3, entry for Tenofovir with emtricitabine and efavirenz

(a) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4470":* **Continuing treatment** *substitute:* **Continuing**

(b) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4522":* **Initial treatment** *substitute:* **Initial**

[36] Schedule 3, entry for Zidovudine

(a) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4454":* **Continuing treatment** *substitute:* **Continuing**

(b) *omit from the text in the column headed "Circumstances and Purposes" for Circumstances Code "C4512":* **Initial treatment** *substitute:* **Initial**