PB 43 of 2024

National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (May Update) Instrument 2024

National Health Act 1953

I, NIKOLAI TSYGANOV, Assistant Secretary, Pricing and PBS Policy Branch, Technology Assessment and Access Division, Department of Health and Aged Care, delegate of the Minister for Health and Aged Care, make this Instrument under subsection 100(2) of the *National Health Act 1953*.

Dated 29 April 2024

NIKOLAI TSYGANOV
Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division

Contents

1 Name

(1) This instrument is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (May Update) Instrument 2024.*

(2) This instrument may also be cited as PB 43 of 2024.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. *The whole of this instrument*	*1 May 2024*	*1 May 2024*

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 100(2) of the *National Health Act 1953*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Highly Specialised Drugs Program) Special Arrangement 2021 (PB 27 of 2021)

[1] Part 1, Division 1, Section 6, definition for "CAR drug"

substitute:

CAR drug (short for Complex Authority Required drug) means any of the following highly specialised drugs:

(a) abatacept;
(b) adalimumab;
(c) ambrisentan;
(d) avatrombopag;
(e) azacitidine;
(f) benralizumab;
(g) bosentan;
(h) burosumab;
(i) difelikefalin;
(j) dupilumab;
(k) eculizumab;
(l) elexacaftor with tezacaftor and with ivacaftor, and ivacaftor;
(m) eltrombopag;
(n) epoprostenol;
(o) etanercept;
(p) iloprost;
(q) infliximab;
(r) ivacaftor;
(s) lenalidomide;
(t) lumacaftor with ivacaftor;

(u) macitentan;
(v) mepolizumab;
(w) midostaurin;
(x) nusinersen;
(y) omalizumab;
(z) onasemnogene abeparvovec;
(aa) pasireotide;
(bb) pegcetacoplan;
(cc) pegvisomant;
(dd) pomalidomide;
(ee) ravulizumab;
(ff) riociguat;
(gg) risdiplam;
(hh) romiplostim;
(ii) selexipag;
(jj) selinexor;
(kk) sildenafil;
(ll) tadalafil;
(mm) teduglutide;
(nn) tezacaftor with ivacaftor and ivacaftor;
(oo) tocilizumab;
(pp) ustekinumab;
(qq) vedolizumab.

[2] Schedule 1, entry for Ambrisentan in each of the forms: Tablet 5 mg; and Tablet 10 mg

omit from the column headed "Circumstances" (all instances): **C13580**

[3] Schedule 1, entry for Bosentan in each of the forms: Tablet 62.5 mg (as monohydrate); and Tablet 125 mg (as monohydrate)

omit from the column headed "Circumstances" (all instances): **C13580**

[4] **Schedule 1, entry for Burosumab in each of the forms: Solution for injection 10 mg in 1 mL; Solution for injection 20 mg in 1 mL; and Solution for injection 30 mg in 1 mL**

omit from the column headed "Circumstances": **C13400**

[5] **Schedule 1, after entry for Desferrioxamine in the form Powder for injection containing desferrioxamine mesilate 2 g**

insert:

Difelikefalin	Solution for I.V. injection 50 micrograms (as acetate) in 1 mL	Injection	Korsuva	C15171 C15211 C15227	See Schedule 2	See Schedule 2

[6] **Schedule 1, entry for Eltrombopag in each of the forms: Tablet 25 mg (as olamine); and Tablet 50 mg (as olamine)**

insert in numerical order in the column headed "Circumstances": **C15173 C15174 C15191 C15192**

[7] **Schedule 1, entry for Epoprostenol in each of the forms: Powder for I.V. infusion 500 micrograms (as sodium); Powder for I.V. infusion 500 micrograms (as sodium) with 2 vials diluent 50 mL; Powder for I.V. infusion 1.5 mg (as sodium); and Powder for I.V. infusion 1.5 mg (as sodium) with 2 vials diluent 50 mL**

omit from the column headed "Circumstances": **C13492**

[8] **Schedule 1, entry for Iloprost**

omit from the column headed "Circumstances": **C13492**

[9] **Schedule 1, entry for Macitentan**

omit from the column headed "Circumstances": **C13580**

[10] **Schedule 1, entry for Pegcetacoplan**

omit from the column headed "Circumstances": **C13658**

[11] **Schedule 1, entry for Selinexor**

substitute:

Selinexor	Tablet 20 mg	Oral	Xpovio	C14021 C14022 C14023 C14024 C14031 C14037 C14039 C14045	See Schedule 2	See Schedule 2

[12] Schedule 1, entry for Sildenafil

omit from the column headed "Circumstances" (all instances): **C13671**

[13] Schedule 1, entry for Tacrolimus in the form Capsule 0.5 mg (once daily prolonged release)

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

		Tacrolimus XR Sandoz	C5569 C9697	60	5

[14] Schedule 1, entry for Tacrolimus in the form Capsule 1 mg (once daily prolonged release)

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

		Tacrolimus XR Sandoz	C5569 C9697	120	5

[15] Schedule 1, entry for Tacrolimus in the form Capsule 3 mg (once daily prolonged release)

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

		Tacrolimus XR Sandoz	C5569 C9697	100	3

[16] Schedule 1, entry for Tacrolimus in the form Capsule 5 mg (once daily prolonged release)

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

		Tacrolimus XR Sandoz	C5569 C9697	60	5

[17] Schedule 1, entry for Tadalafil

omit from the column headed "Circumstances" (all instances): **C13671**

[18] Schedule 1, entry for Tenofovir with emtricitabine in the form Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg

omit:

		Tenofovir Disoproxil Emtricitabine Mylan 300/200	C6985 C6986	60	5

[19] **Schedule 2, entry for Ambrisentan**

omit from the column headed "Circumstances": **C13580**

[20] **Schedule 2, entry for Bosentan *[Maximum Quantity: Sufficient for treatment for 1 month; Maximum Repeats: 5]***

omit from the column headed "Circumstances": **C13580**

[21] **Schedule 2, entry for Burosumab**

omit from the column headed "Circumstances": **C13400**

[22] **Schedule 2, after entry for Burosumab**

insert:

Difelikefalin	C15171	Sufficient for treatment for 4 weeks	2
	C15211 C15227	Sufficient for treatment for 4 weeks	5

[23] **Schedule 2, entry for Eltrombopag**

substitute:

Eltrombopag	C13327 C14126 C14127 C14129	1 pack	5
	C15192	3 packs	3
	C15173 C15174 C15191	3 packs	5

[24] **Schedule 2, entry for Epoprostenol**

omit from the column headed "Circumstances": **C13492**

[25] **Schedule 2, entry for Iloprost**

omit from the column headed "Circumstances": **C13492**

[26] **Schedule 2, entry for Macitentan**

omit from the column headed "Circumstances": **C13580**

[27] **Schedule 2, entry for Pegcetacoplan *[Maximum Quantity: Sufficient for treatment for 4 weeks; Maximum Repeats: 5]***

omit from the column headed "Circumstances": **C13658**

[28] Schedule 2, after entry for Selexipag *[Maximum Quantity: 140; Maximum Repeats: Sufficient for treatment for 12 weeks]*

insert:

Selinexor	C14021 C14022 C14045	16	2
	C14023 C14024 C14037	20	2
	C14031 C14039	32	2

[29] Schedule 2, entry for Sildenafil

omit from the column headed "Circumstances": **C13671**

[30] Schedule 2, entry for Tadalafil

omit from the column headed "Circumstances": **C13671**

[31] Schedule 3, entry for Ambrisentan, omit entry for Circumstances Code "C13580"

[32] Schedule 3, entry for Bosentan, omit entry for Circumstances Code "C13580"

[33] Schedule 3, entry for Burosumab, omit entry for Circumstances Code "C13400"

[34] Schedule 3, after entry for Desferrioxamine

insert:

Difelikefalin	C15171		Moderate to severe pruritus (itching) associated with chronic kidney disease Initial treatment Patient must be on optimised haemodialysis; AND Patient must be on haemodialysis for at least 3 months; AND The condition must be confirmed based on both physical examination and patient history to exclude any factors that may be triggering the pruritus; AND Patient must have experienced itch that persists for at least 6 weeks despite best supportive care; AND Patient must have a 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) baseline score of more than 4; AND Patient must not receive more than 12 weeks of treatment under this restriction. Must be treated by a nephrologist. Patient must be at least 18 years of age. Prescriber must exclude any other causes of pruritus which include any of the following:	Compliance with Authority Required procedures

			(i) drug/dialysis related (e.g., opioid-related pruritus); (ii) drug hypersensitivity or adverse effect; contact dermatitis; allergy; (iii) differential diagnoses (e.g., xerosis; infestations; iron deficiency; liver disease; polycythaemia vera/leukemia/lymphoma; hypothyroidism; uncontrolled diabetes). Best supportive care for patients with chronic kidney disease-associated pruritus is not limited to but includes: (i) optimisation of dialysis; (ii) skin hydration and nutrition (with the use of moisturiser, emollients, barrier creams or oils); (iii) patient education on the importance of avoiding or minimising scratching. Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records. At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 2 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.	
	C15211		Moderate to severe pruritus (itching) associated with chronic kidney disease Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug including at least a 3-point improvement from baseline in 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) score. Must be treated by a nephrologist; OR Must be treated by a medical practitioner in consultation with a nephrologist. Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records. At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 5 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.	Compliance with Authority Required procedures
	C15227		Moderate to severe pruritus (itching) associated with chronic kidney disease Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024; AND	Compliance with Authority Required procedures

			Patient must have met all other PBS eligibility criteria that a non-'Grandfather' patient would ordinarily be required to meet, meaning that at the time non-PBS-subsidised supply was commenced, the patient: (i) was on optimised haemodialysis; (ii) was on haemodialysis for at least 3 months; (iii) had a condition confirmed based on both physical examination and patient history to exclude any factors that may be triggering the pruritus; (iv) had experienced itch that persists for at least 6 weeks despite best supportive care; (v) had a 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) of more than 4 at baseline; AND Patient must have demonstrated an adequate response to the most recent non-PBS-subsidised treatment with this drug for this condition, including at least a 3-point improvement from baseline in 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) score. Must be treated by a nephrologist. Patient must be at least 18 years of age. Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records. At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 5 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.	

[35] Schedule 3, entry for Eltrombopag

insert in numerical order after existing text:

	C15173		Severe aplastic anaemia Continuing treatment - Second line treatment The condition must be severe aplastic anaemia; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction; AND Patient must have demonstrated a response to PBS-subsidised treatment with this drug. Platelet, haemoglobin and neutrophil counts must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records. Once platelet count is greater than 50 x 109/L, haemoglobin is greater than 100 g/L in the absence of red blood cell (RBC) transfusion, and absolute neutrophil (ANC) is greater than 1 x 109/L for more than 8 weeks, the dose of eltrombopag should be reduced as per the Product Information. For the purposes of this restriction, a response is defined as no longer meeting the criteria for severe aplastic anaemia.	Compliance with Authority Required procedures
	C15174		Severe aplastic anaemia	Compliance with Authority

			Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements - First line treatment Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024; AND The condition must be severe aplastic anaemia; AND Patient must not have received treatment with immunosuppressive therapy for this condition prior to initiating non-PBS-subsidised treatment; AND The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin; AND Patient must be considered ineligible for haemopoietic stem cell transplant; AND Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). A patient may qualify for PBS-subsidised treatment under this restriction once only.	Required procedures
	C15191		Severe aplastic anaemia First line treatment The condition must be severe aplastic anaemia; AND Patient must not have received treatment with immunosuppressive therapy for this condition; AND The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin; AND Patient must be considered ineligible for haemopoietic stem cell transplant; AND Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Authority Required procedures
	C15192		Severe aplastic anaemia Initial treatment - Second line treatment The condition must be severe aplastic anaemia; AND Patient must not have achieved an adequate response to prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin; OR Patient must have relapsed following prior immunosuppressive therapy including anti-thymocyte	Compliance with Written Authority Required procedures

			antibody and ciclosporin; AND Patient must not receive more than 16 weeks of treatment under this restriction. The authority application must be made via the online PBS Authorities (real time assessment), or in writing via HPOS form upload or mail and must include: (a) prior immunosuppressive therapy, including dates of treatment. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	

[36] Schedule 3, entry for Epoprostenol, omit entry for Circumstances Code "C13492"

[37] Schedule 3, entry for Iloprost, omit entry for Circumstances Code "C13492"

[38] Schedule 3, entry for Macitentan, omit entry for Circumstances Code "C13580"

[39] Schedule 3, entry for Pegcetacoplan, omit entry for Circumstances Code "C13658"

[40] Schedule 3, entry for Selinexor

(a) *for the entry for Circumstances Code "C14021", omit from the column headed "Purposes Code":* **P14021**

(b) *for the entry for Circumstances Code "C14022", omit from the column headed "Purposes Code":* **P14022**

(c) *for the entry for Circumstances Code "C14023", omit from the column headed "Purposes Code":* **P14023**

(d) *for the entry for Circumstances Code "C14024", omit from the column headed "Purposes Code":* **P14024**

(e) *for the entry for Circumstances Code "C14031", omit from the column headed "Purposes Code":* **P14031**

(f) *for the entry for Circumstances Code "C14037", omit from the column headed "Purposes Code":* **P14037**

(g) *for the entry for Circumstances Code "C14039", omit from the column headed "Purposes Code":* **P14039**

(h) *for the entry for Circumstances Code "C14045", omit from the column headed "Purposes Code":* **P14045**

[41] Schedule 3, entry for Sildenafil, omit entry for Circumstances Code "C13671"

[42] Schedule 3, entry for Tadalafil, omit entry for Circumstances Code "C13671"