PB 44 of 2025

National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (May Update) Instrument 2025

National Health Act 1953

I, REBECCA RICHARDSON, 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 28 April 2025

REBECCA RICHARDSON
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 2025.*

(2) This instrument may also be cited as PB 44 of 2025.

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 2025*	*1 May 2025*

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 of *CAR drug*)

Repeal the definition, substitute:

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

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

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

[2] Part 1, Division 1, Section 6 (definition of *community access medication)*

Repeal the definition, substitute:

community access medication means any of the following:

(a) medication for the treatment of hepatitis B;

(b) medication for the treatment of HIV or AIDS, other than a pharmaceutical benefit that has the drug:

(i) azithromycin; or

(ii) doxorubicin - pegylated liposomal; or

(iii) rifabutin;

(c) medication for the treatment of opioid dependence;

(d) medication for continuing treatment of schizophrenia;

(e) edaravone, if it is for continuing treatment;

(f) lanreotide;

(g) octreotide, if:

(i) the description of its form includes "Injection (modified release)"; and

(ii) it is for continuing treatment.

[3] Part 1, Division 1, Subsection 7(4)

Repeal the subsection (including the heading), substitute:

Medical practitioners—medication for the treatment of hepatitis C, edaravone, lanreotide and octreotide

(4) A medical practitioner is an ***authorised prescriber*** for the following HSD pharmaceutical benefits:

(a) a benefit that has a drug that is a medication for the treatment of hepatitis C;

(b) a benefit that has the drug edaravone, if it is for continuing treatment;

(c) a benefit that has the drug lanreotide;

(d) a benefit that has the drug octreotide, if:

(i) the description of its form includes "Injection (modified release)"; and

(ii) it is for continuing treatment.

[4] Schedule 1, entry for Adefovir

omit:

Tablet containing adefovir dipivoxil 10 mg (S19A)	Oral	Adefovir Dipivoxil Tablets 10 mg	C4490 C4510	60	5	

			(SigmaPharm Laboratories)				

[5] Schedule 1, after entry for Azacitidine *[Brand: Azacitidine Sandoz]*

insert:

			Azacitidine SXP	C12439 C12983 C12986 C13010 C13011 C13012 C13015 C13029		See Schedule 2	See Schedule 2

[6] Schedule 1, after entry for Bosentan in the form Tablet 125 mg (as monohydrate) *[Brand: Bosentan RBX]*

insert:

			Bosentan Viatris	C11229 C13495 C13496 C13497 C13499 C13571 C13582 C13632		See Schedule 2	See Schedule 2

[7] Schedule 1, entry for Difelikefalin

omit from the column headed "Circumstances": **C15227**

[8] Schedule 1, after entry for Eculizumab

insert:

Edaravone	Solution concentrate for I.V. infusion 30 mg in 20 mL	Injection	Radicava	C16435 C16479	P16479	20	2
				C16435 C16479	P16435	28	0

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

(a) *omit from the column headed "Circumstances":* **C15174 C15191**

(b) *insert in numerical order in the column headed "Circumstances":* **C16455**

[10] Schedule 1, after entry for Epoprostenol in the form Powder for I.V. infusion 1.5 mg (as sodium)

insert:

Esketamine	Nasal spray device 28 mg in 2 actuations	Nasal	Spravato	C16416 C16419 C16421 C16422 C16438 C16454 C16460 C16470 C16477	P16421 P16460	4	5
				C16416 C16419 C16421 C16422 C16438 C16454 C16460 C16470 C16477	P16477	8	0
				C16416 C16419 C16421 C16422 C16438 C16454 C16460 C16470 C16477	P16438 P16470	8	5
				C16416 C16419 C16421 C16422 C16438 C16454 C16460 C16470 C16477	P16416 P16419	12	5
				C16416 C16419 C16421 C16422 C16438 C16454 C16460 C16470 C16477	P16422	16	0
				C16416 C16419 C16421 C16422 C16438 C16454 C16460 C16470 C16477	P16454	24	0

[11] Schedule 1, after entry for Macitentan

insert:

Macitentan with tadalafil	Tablet containing 10 mg macitentan with 40 mg tadalafil	Oral	Opsynvi	C16433 C16457	See Schedule 2	See Schedule 2

[12] **Schedule 1, after entry for Tenofovir with emtricitabine in the form Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg *[Brand: CIPLA TENOFOVIR + EMTRICITABINE 300/200]***

insert:

		TENOFOVIR/EMTRICITABINE 300/200 APX	C6985 C6986	60	5

[13] **Schedule 1, after entry for Vedolizumab**

insert:

Vutrisiran	Injection 25 mg (as sodium) in 0.5 mL pre-filled syringe	Injection	Amvuttra	C16408 C16434 C16446	See Schedule 2	See Schedule 2

[14] **Schedule 2, entry for Difelikefalin *[Maximum quantity: Sufficient for treatment for 4 weeks; Maximum repeats: 5]***

omit from the column headed "Circumstances": **C15227**

[15] **Schedule 2, entry for Eltrombopag *[Maximum quantity: 3 packs; Maximum repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15174 C15191**

(b) *insert in numerical order in the column headed "Circumstances":* **C16455**

[16] **Schedule 2, after entry for Macitentan**

insert:

Macitentan with tadalafil	C16433 C16457	1 pack	5

[17] **Schedule 2, after entry for Vedolizumab *[Maximum quantity: 1; Maximum repeats: Sufficient for treatment for 24 weeks]***

insert:

Vutrisiran	C16408 C16434 C16446	1	1

[18] **Schedule 3, entry for Difelikefalin**

omit:

	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	Compliance with Authority Required procedures

			1 May 2024; AND 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.	

[19] Schedule 3, after entry for Eculizumab

insert:

Edaravone	C16435	P16435	Amyotrophic lateral sclerosis Initial treatment The condition must be/have been diagnosed by a neurologist; AND Patient must not have had symptoms for more than 2 years prior to commencing therapy with this drug; AND Patient must have at least 80 percent of predicted forced vital capacity (FVC) or slow vital capacity (SVC) within the 2 months prior to commencing therapy with this drug; AND Patient must not require assistance with eating or ambulation; AND Patient must have at least two points on each individual item of the ALS Functional Rating Scale - Revised (ALSFRS-R) score prior to commencing therapy with this drug; AND Patient must not have undergone a tracheostomy; AND Patient must not have experienced respiratory failure. The date of diagnosis, the date and results of spirometry (in terms of percent of predicted forced vital capacity or slow vital capacity) must be supplied with the initial authority application.	Compliance with Authority Required procedures

	C16479	P16479	Amyotrophic lateral sclerosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have undergone a tracheostomy; AND Patient must not have experienced respiratory failure.	Compliance with Authority Required procedures

[20] Schedule 3, entry for Eltrombopag

(a) *omit:*

	C15174		Severe aplastic anaemia 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.	Compliance with Authority 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	Compliance with Authority Required procedures

			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).	

(b) *insert in numerical order after existing text:*

	C16455		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) details of the proposed prescription; 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

[21] Schedule 3, after entry for Epoprostenol

insert:

Esketamine	C16416	P16416	Treatment resistant major depression Transitioning from non-PBS to PBS-subsided treatment - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this indication prior to 1 May 2025; AND The condition must have been inadequately responsive to at least two anti-depressant drug therapies prior to commencing non-PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed each of: (i) an administered dose beyond 84 mg, (ii) a quantity of drug, after accounting for repeat prescriptions plus different pack sizes where prescribed, that would exceed a quantity sufficient to treat the patient for 24 weeks; AND Patient must have demonstrated adequate response to treatment with esketamine after the 4-week induction and every 6 months thereafter as evaluated by a structured clinical rating scale (evidence of scores and justification of demonstration of response must be retained in the patient's	Compliance with Authority Required procedures

			medical records). Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist; AND Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine. The listed quantity of 12 units of nasal spray is intended for a dosage of 84 mg per treatment administration for patients transitioning from non-PBS to PBS-subsidised treatment.	
	C16419	P16419	Treatment resistant major depression Non-induction treatment The treatment must be to continue existing PBS-subsidised treatment for this indication; AND The treatment must not exceed each of: (i) an administered dose beyond 84 mg, (ii) a quantity of drug, after accounting for repeat prescriptions plus different pack sizes where prescribed, that would exceed a quantity sufficient to treat the patient for 24 weeks; AND Patient must have demonstrated adequate response to treatment with esketamine after the 4-week induction and every 6 months thereafter as evaluated by a structured clinical rating scale (evidence of scores and justification of demonstration of response must be retained in the patient's medical records). Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist; AND Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine. The listed quantity of 12 units of nasal spray is intended for a dosage of 84 mg per treatment administration in the non-induction treatment setting.	Compliance with Authority Required procedures
	C16421	P16421	Treatment resistant major depression Transitioning from non-PBS to PBS-subsided treatment - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this indication prior to 1 May 2025; AND The condition must have been inadequately responsive to at least two anti-depressant drug therapies prior to commencing non-PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed each of: (i) an administered dose beyond 84 mg, (ii) a quantity of drug, after accounting for repeat prescriptions plus different pack sizes where prescribed, that would exceed a quantity sufficient to treat the patient for 24 weeks; AND Patient must have demonstrated adequate response to treatment with esketamine after the 4-week induction and every 6 months thereafter as evaluated by a structured clinical rating scale (evidence of scores and justification of demonstration of response must be retained in the patient's medical records).	Compliance with Authority Required procedures

			Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist; AND Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine. The listed quantity of 4 units of nasal spray is intended for a dosage of 28 mg per treatment administration for patients transitioning from non-PBS to PBS-subsidised treatment.	
	C16422	P16422	Treatment resistant major depression Induction treatment The condition must have been inadequately responsive to at least two oral anti-depressant drug therapies. Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist; AND Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine. The following must apply if reinitiating treatment: (i) at least four-week gap from last treatment course to reinitiation of treatment; and (ii) evidence, documented in the patient's medical record using a structured rating scale, of significant clinical therapeutic benefit of the prior course of treatment with esketamine; and (iii) evidence, documented in the patient's medical record using a structured rating scale, of a relapse in depression. The listed quantity of 16 units of nasal spray is intended for a dosage of 56 mg per treatment administration in the induction treatment setting.	Compliance with Authority Required procedures
	C16438	P16438	Treatment resistant major depression Transitioning from non-PBS to PBS-subsided treatment - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this indication prior to 1 May 2025; AND The condition must have been inadequately responsive to at least two anti-depressant drug therapies prior to commencing non-PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed each of: (i) an administered dose beyond 84 mg, (ii) a quantity of drug, after accounting for repeat prescriptions plus different pack sizes where prescribed, that would exceed a quantity sufficient to treat the patient for 24 weeks; AND Patient must have demonstrated adequate response to treatment with esketamine after the 4-week induction and every 6 months thereafter as evaluated by a structured clinical rating scale (evidence of scores and justification of demonstration of response must be retained in the patient's medical records). Must be treated by a psychiatrist, where prescribing must also be completed by the treating	Compliance with Authority Required procedures

			psychiatrist; AND Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine. The listed quantity of 8 units of nasal spray is intended for a dosage of 56 mg per treatment administration for patients transitioning from non-PBS to PBS-subsidised treatment.	
	C16454	P16454	Treatment resistant major depression Induction treatment The condition must have been inadequately responsive to at least two oral anti-depressant drug therapies. Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist; AND Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine. The following must apply if reinitiating treatment: (i) at least four-week gap from last treatment course to reinitiation of treatment; and (ii) evidence, documented in the patient's medical record using a structured rating scale, of significant clinical therapeutic benefit of the prior course of treatment with esketamine; and (iii) evidence, documented in the patient's medical record using a structured rating scale, of a relapse in depression. The listed quantity of 24 units of nasal spray is intended for a dosage of 84 mg per treatment administration in the induction treatment setting.	Compliance with Authority Required procedures
	C16460	P16460	Treatment resistant major depression Non-induction treatment The treatment must be to continue existing PBS-subsidised treatment for this indication; AND The treatment must not exceed each of: (i) an administered dose beyond 84 mg, (ii) a quantity of drug, after accounting for repeat prescriptions plus different pack sizes where prescribed, that would exceed a quantity sufficient to treat the patient for 24 weeks; AND Patient must have demonstrated adequate response to treatment with esketamine after the 4-week induction and every 6 months thereafter as evaluated by a structured clinical rating scale (evidence of scores and justification of demonstration of response must be retained in the patient's medical records). Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist; AND Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine. The listed quantity of 4 units of nasal spray is intended for a dosage of 28 mg per treatment	Compliance with Authority Required procedures

			administration in the non-induction treatment setting.	
	C16470	P16470	Treatment resistant major depression Non-induction treatment The treatment must be to continue existing PBS-subsidised treatment for this indication; AND The treatment must not exceed each of: (i) an administered dose beyond 84 mg, (ii) a quantity of drug, after accounting for repeat prescriptions plus different pack sizes where prescribed, that would exceed a quantity sufficient to treat the patient for 24 weeks; AND Patient must have demonstrated adequate response to treatment with esketamine after the 4-week induction and every 6 months thereafter as evaluated by a structured clinical rating scale (evidence of scores and justification of demonstration of response must be retained in the patient's medical records). Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist; AND Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine. The listed quantity of 8 units of nasal spray is intended for a dosage of 56 mg per treatment administration in the non-induction treatment setting.	Compliance with Authority Required procedures
	C16477	P16477	Treatment resistant major depression Induction treatment The condition must have been inadequately responsive to at least two oral anti-depressant drug therapies. Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist; AND Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine. The following must apply if reinitiating treatment: (i) at least four-week gap from last treatment course to reinitiation of treatment; and (ii) evidence, documented in the patient's medical record using a structured rating scale, of significant clinical therapeutic benefit of the prior course of treatment with esketamine; and (iii) evidence, documented in the patient's medical record using a structured rating scale, of a relapse in depression. The listed quantity of 8 units of nasal spray is intended for a dosage of 28 mg per treatment administration in the induction treatment setting.	Compliance with Authority Required procedures

[22] Schedule 3, entry for Infliximab

omit from the column headed "Authority Requirements—Part of Circumstances" for Circumstances Code "C13691": **Compliance with Authority Required procedures** *substitute:* **Compliance with Written Authority Required procedures**

[23] Schedule 3, after entry for Macitentan

insert:

Macitentan with tadalafil	C16433		Pulmonary arterial hypertension (PAH) Continuing treatment of combination therapy (triple therapy with selexipag) The treatment must be part of triple combination therapy consisting of: (i) macitentan, (ii) tadalafil, (iii) selexipag. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH; AND Patient must be undergoing continuing treatment of existing PBS-subsidised macitentan and tadalafil as part of combination therapy (triple therapy with selexipag) where macitentan and tadalafil and their doses in the combination remain unchanged from the previous authority application. This treatment is not PBS-subsidised for the use as initial therapy The authority application for selexipag must be approved prior to the authority application for this agent.	Compliance with Authority Required procedures
	C16457		Pulmonary arterial hypertension (PAH) Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag) The treatment must be dual combination therapy as a fixed dose combination consisting of: (i) macitentan, (ii) tadalafil; OR The treatment must be part of triple combination therapy as a fixed dose combination consisting of: (i) macitentan, (ii) tadalafil, (iii) one prostanoid. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH; AND Patient must be undergoing continuing treatment of existing PBS-subsidised macitentan and tadalafil as part of combination therapy (dual or triple therapy, excluding selexipag) where macitentan and tadalafil and their doses in the combination remain unchanged from the previous authority application. This treatment is not PBS-subsidised for the use as initial therapy For the purposes of PBS subsidy, a prostanoid is one of: (a) epoprostenol, (b) iloprost Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to	Compliance with Authority Required procedures

			be considered as 'combination' therapy.	

[24] Schedule 3, entry for Vedolizumab

omit from the column headed "Authority Requirements—Part of Circumstances" for Circumstances Code "C16239": **Compliance with Authority Required procedures** *substitute:* **Compliance with Written Authority Required procedures**

[25] Schedule 3, after entry for Vedolizumab

insert:

Vutrisiran	C16408		Hereditary transthyretin amyloidosis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have received treatment with this drug for this condition prior to 1 May 2025; AND Patient must continue to demonstrate clinical benefit; AND Patient must have had a Polyneuropathy Disability (PND) score description of either I, II, IIIA, IIIB prior to commencing non-PBS-subsidised therapy; OR Patient must have had a Familial Amyloid Polyneuropathy (FAP) stage description of 1 or 2 prior to commencing non-PBS-subsidised therapy; AND Patient must not have exhibited heart failure symptoms (defined as New York Heart Association [NYHA] class III or IV) prior to commencing non-PBS-subsidised therapy; AND Patient must not have previously undergone a liver transplant; AND Patient must not be permanently bedridden; OR Patient must not be receiving end-of-life care. Must be treated by a consultant with experience in the management of amyloid disorders or in consultation with a consultant with experience in the management of amyloid disorders; AND Patient must be undergoing treatment with this drug as a monotherapy (i.e. not in combination with any other disease modifying medicines for amyloidosis disorders). Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) details of the proposed prescription; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Written Authority Required procedures
	C16434		Hereditary transthyretin amyloidosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition;	Compliance with Written Authority Required procedures

			AND Patient must continue to demonstrate clinical benefit; AND Patient must not have previously undergone a liver transplant; AND Patient must not be permanently bedridden; OR Patient must not be receiving end-of-life care. Must be treated by a consultant with experience in the management of amyloid disorders or in consultation with a consultant with experience in the management of amyloid disorders; AND Patient must be undergoing treatment with this drug as a monotherapy (i.e. not in combination with any other disease modifying medicines for amyloidosis disorders). Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) details of the proposed prescription; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
	C16446		Hereditary transthyretin amyloidosis Initial treatment Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication; AND The condition must be hereditary transthyretin amyloidosis confirmed by genetic testing; AND Patient must have a Polyneuropathy Disability (PND) score description of either I, II, IIIA, IIIB; OR Patient must have a Familial Amyloid Polyneuropathy (FAP) stage description of 1 or 2; AND Patient must not have previously undergone a liver transplant; AND Patient must not exhibit heart failure symptoms (defined as New York Heart Association NYHA class III or IV). Must be treated by a consultant with experience in the management of amyloid disorders or in consultation with a consultant with experience in the management of amyloid disorders; AND Patient must be undergoing treatment with this drug as a monotherapy (i.e. not in combination with any other disease modifying medicines for amyloidosis disorders). Patient must have either: (i) stage 1 polyneuropathy, (ii) stage 2 polyneuropathy; AND Patient must be at least 18 years of age. PND scores in the context of this PBS restriction are: Stage 0 - No symptoms; Stage I - Sensory disturbances but preserved walking capability; Stage II - Impaired walking capacity but able to walk without stick or crutches;	Compliance with Written Authority Required procedures

			Stage IIIA - Walking with help of one stick or crutch; Stage IIIB - Walking with help of two sticks or crutches; Stage IV - Confined to wheelchair or bedridden. FAP stage in the context of this PBS restriction are: Stage 0 - No symptoms; Stage 1 - Unimpaired ambulation; Stage 2 - Assistance with ambulation required; Stage 3 - Wheelchair-bound or bedridden. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) details of the proposed prescription; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	