PB 13 of 2025

National Health (Listing of Pharmaceutical Benefits) Amendment (March 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 sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

Dated 24 February 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 (Listing of Pharmaceutical Benefits) Amendment (March Update) Instrument 2025*.

(2) This Instrument may also be cited as PB 13 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 March 2025*	*1 March 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Note: This table relates only to the provisions of this instrument as originally made.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 sections 84AF, 84AK, 85, 85A, 88 and 101 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 (Listing of Pharmaceutical Benefits) Instrument 2024 (PB 26 of 2024)

[1] Schedule 1, Part 1, after entry for Acarbose in the form Tablet 50 mg *[Brand: GLYBOSAY; Maximum Quantity: 180; Number of Repeats: 5]*

insert:

Acarbose	Tablet 50 mg (S19A)	Oral	Acarbose 50 mg tablets (Morningside, UK)	DZ	MP NP		90	5	90
Acarbose	Tablet 50 mg (S19A)	Oral	Acarbose 50 mg tablets (Morningside, UK)	DZ	MP NP	P14238	180	5	90

[2] Schedule 1, Part 1, after entry for Acarbose in the form Tablet 100 mg *[Brand: GLYBOSAY; Maximum Quantity: 180; Number of Repeats: 5]*

insert:

Acarbose	Tablet 100 mg (S19A)	Oral	Acarbose 100 mg tablets (Morningside, UK)	DZ	MP NP		90	5	90
Acarbose	Tablet 100 mg (S19A)	Oral	Acarbose 100 mg tablets (Morningside, UK)	DZ	MP NP	P14238	180	5	90

[3] Schedule 1, Part 1, entries for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Brand: Hadlima]*

omit from the column headed "Responsible Person" (all instances): OQ *substitute (all instances):* RF

[4] Schedule 1, Part 1, entries for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Hadlima]*

omit from the column headed "Responsible Person" (all instances): OQ *substitute (all instances):* RF

[5] Schedule 1, Part 1, after entry for Adalimumab in the form Injection 80 mg in 0.8 mL pre-filled pen *[Brand: Humira; Maximum Quantity: 3; Number of Repeats: 0]*

insert:

Adalimumab	Injection 80 mg in 0.8 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C12103 C12105 C12155 C12212 C14398 C14399	P12103 P12105 P12155 P12212 P14398 P14399	1	0	1
Adalimumab	Injection 80 mg in 0.8 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C15788	P15788	2	2	1
Adalimumab	Injection 80 mg in 0.8 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C11529 C15777 C15796	P11529 P15777 P15796	2	5	1
Adalimumab	Injection 80 mg in 0.8 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12152 C12229 C15764 C15765 C15795	P11715 P11716 P11759 P11761 P11762 P11763 P11852 P11854 P11855 P12152 P12229 P15764 P15765 P15795	3	0	1

[6] Schedule 1, Part 1, entries for Amoxicillin with clavulanic acid

omit:

Amoxicillin with clavulanic acid	Powder for oral suspension containing 125 mg amoxicillin (as trihydrate) with 31.25 mg clavulanic acid (as potassium clavulanate) per 5 mL, 100 mL (S19A)	Oral	CLAVULIN-125F (GlaxoSmithKline, Canada)	DZ	PDP	C5833 C5894	P5833 P5894	1	0	1
Amoxicillin with clavulanic acid	Powder for oral suspension containing 125 mg amoxicillin (as trihydrate) with 31.25 mg clavulanic acid (as potassium clavulanate) per 5 mL, 100 mL (S19A)	Oral	CLAVULIN-125F (GlaxoSmithKline, Canada)	DZ	MP NP	C5832 C5893	P5832 P5893	1	1	1

[7] Schedule 1, Part 1, entries for Azithromycin

omit:

Azithromycin	Powder for oral suspension 200 mg (as dihydrate) per	Oral	Azithromycin (Zydus, USA)	DZ	MP NP	C5637		1	0	1

	5 mL, 15 mL (S19A)										

[8] Schedule 1, Part 1, entries for Betaxolol

omit:

Betaxolol	Eye drops, solution, 5 mg (as hydrochloride) per mL, 5 mL	Application to the eye	BetoQuin	NM	MP AO		1	5	1		
Betaxolol	Eye drops, solution, 5 mg (as hydrochloride) per mL, 5 mL	Application to the eye	BetoQuin	NM	MP AO	P14238	2	5	1		

[9] Schedule 1, Part 1, entries for Blinatumomab

substitute:

Blinatumomab	Powder for I.V. infusion 38.5 micrograms	Injection	Blincyto	AN	MP	C9369 C9519 C16292 C16308 C16334 C16341	See Note 3	See Note 3	1	D(100)

[10] Schedule 1, Part 1, entries for Cladribine in the form Tablet 10 mg

substitute:

Cladribine	Tablet 10 mg	Oral	Mavenclad	SG	MP NP	C16299 C16345	P16299 P16345	1	1	1	
Cladribine	Tablet 10 mg	Oral	Mavenclad	SG	MP NP	C16299 C16345	P16299 P16345	6	1	6	
Cladribine	Tablet 10 mg	Oral	Mavenclad	SG	MP NP	C16299 C16345	P16299 P16345	8	1	4	

[11] Schedule 1, Part 1, entries for Dimethyl fumarate in the form Capsule (modified release) 120 mg

(a) omit from the column headed "Authorised Prescriber" (all instances): MP *substitute (all instances):* MP NP

(b) omit from the column headed "Circumstances" (all instances): C10139 C10140 *substitute (all instances):* C16315 C16323

[12] Schedule 1, Part 1, entries for Dimethyl fumarate in the form Capsule (modified release) 240 mg

(a) omit from the column headed "Authorised Prescriber" (all instances): MP *substitute (all instances):* MP NP

(b) omit from the column headed "Circumstances" (all instances): C10139 *substitute (all instances):* C16315

[13] Schedule 1, Part 1, entry for Diroximel fumarate

(a) omit from the column headed "Authorised Prescriber": MP *substitute:* MP NP

(b) omit from the column headed "Circumstances": C13034 13072 *substitute:* C16315 C16323

[14] Schedule 1, Part 1, after entry for Doxycycline in the form Tablet 100 mg (as monohydrate) *[Maximum Quantity: 56; Number of Repeats: 2]*

insert:

Drospirenone with ethinylestradiol	Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets	Oral	Yasmin	BN	MP NP			3	3	1
Drospirenone with ethinylestradiol	Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets	Oral	Yasmin	BN	MP NP			3	3	3
Drospirenone with ethinylestradiol	Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol (as betadex clathrate) and 4 inert tablets	Oral	Yaz	BN	MP NP			3	3	1
Drospirenone with ethinylestradiol	Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol (as betadex clathrate) and 4 inert tablets	Oral	Yaz	BN	MP NP			3	3	3

[15] Schedule 1, Part 1, entries for Duloxetine in the form Capsule 60 mg (as hydrochloride)

substitute:

Duloxetine	Capsule 60 mg (as hydrochloride)	Oral	APO-Duloxetine	TX	MP NP	C5650	P5650	28	5	28
Duloxetine	Capsule 60 mg (as	Oral	APO-Duloxetine	TX	MP	C15553	P15553	56	2	28

	hydrochloride)				NP					
Duloxetine	Capsule 60 mg (as hydrochloride)	Oral	Duloxecor	CR	MP NP	C5650	P5650	28	5	28
Duloxetine	Capsule 60 mg (as hydrochloride)	Oral	Duloxecor	CR	MP NP	C15553	P15553	56	2	28
Duloxetine	Capsule 60 mg (as hydrochloride)	Oral	Duloxetine Sandoz	HX	MP NP	C5650	P5650	28	5	28
Duloxetine	Capsule 60 mg (as hydrochloride)	Oral	Duloxetine Sandoz	HX	MP NP	C15553	P15553	56	2	28
Duloxetine	Capsule 60 mg (as hydrochloride)	Oral	Duloxetine Sandoz 60	SZ	MP NP	C5650	P5650	28	5	28
Duloxetine	Capsule 60 mg (as hydrochloride)	Oral	Duloxetine Sandoz 60	SZ	MP NP	C15553	P15553	56	2	28
Duloxetine	Capsule 60 mg (as hydrochloride)	Oral	DYTREX 60	RW	MP NP	C5650	P5650	28	5	28
Duloxetine	Capsule 60 mg (as hydrochloride)	Oral	DYTREX 60	RW	MP NP	C15553	P15553	56	2	28
Duloxetine	Capsule 60 mg (as hydrochloride)	Oral	Tixol 60	AL	MP NP	C5650	P5650	28	5	28
Duloxetine	Capsule 60 mg (as hydrochloride)	Oral	Tixol 60	AL	MP NP	C15553	P15553	56	2	28

[16] Schedule 1, Part 1, after entry for Dutasteride with tamsulosin in the form Capsule containing dutasteride 500 micrograms with tamsulosin hydrochloride 400 micrograms *[Brand: Dutasteride/Tamsulosin Lupin 500/400; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Dutasteride with tamsulosin	Capsule containing dutasteride 500 micrograms with tamsulosin hydrochloride 400 micrograms	Oral	Dutasteride/Tamsulosin Sandoz 500/400	SZ	MP NP	C6189	P6189	30	5	30

Dutasteride with tamsulosin	Capsule containing dutasteride 500 micrograms with tamsulosin hydrochloride 400 micrograms	Oral	Dutasteride/Tamsulosin Sandoz 500/400	SZ	MP NP	C15004	P15004	60	5	30

[17] Schedule 1, Part 1, after entry for Enoxaparin in the form Injection containing enoxaparin sodium 20 mg (2,000 I.U. anti-Xa) in 0.2 mL pre-filled syringe *[Brand: Exarane; Maximum Quantity: 20; Number of Repeats: 3]*

insert:

Enoxaparin	Injection containing enoxaparin sodium 20 mg (2,000 I.U. anti-Xa) in 0.2 mL pre-filled syringe	Injection	Exarane Safety-Lock	JO	MP MW NP	C16261	P16261	20	1	10
Enoxaparin	Injection containing enoxaparin sodium 20 mg (2,000 I.U. anti-Xa) in 0.2 mL pre-filled syringe	Injection	Exarane Safety-Lock	JO	MP NP	C4910	P4910	20	3	10

[18] Schedule 1, Part 1, after entry for Enoxaparin in the form Injection containing enoxaparin sodium 40 mg (4,000 I.U. anti-Xa) in 0.4 mL pre-filled syringe *[Brand: Exarane; Maximum Quantity: 20; Number of Repeats: 3]*

insert:

Enoxaparin	Injection containing enoxaparin sodium 40 mg (4,000 I.U. anti-Xa) in 0.4 mL pre-filled syringe	Injection	Exarane Safety-Lock	JO	MP MW NP	C16261	P16261	20	1	10
Enoxaparin	Injection containing enoxaparin sodium 40 mg (4,000 I.U. anti-Xa) in 0.4 mL pre-filled syringe	Injection	Exarane Safety-Lock	JO	MP NP	C4910	P4910	20	3	10

[19] Schedule 1, Part 1, after entry for Enoxaparin in the form Injection containing enoxaparin sodium 60 mg (6,000 I.U. anti-Xa) in 0.6 mL pre-filled syringe *[Brand: Exarane; Maximum Quantity: 20; Number of Repeats: 3]*

insert:

Enoxaparin	Injection containing enoxaparin sodium 60 mg	Injection	Exarane Safety-Lock	JO	MP MW	C16261	P16261	10	1	10

	(6,000 I.U. anti-Xa) in 0.6 mL pre-filled syringe				NP					
Enoxaparin	Injection containing enoxaparin sodium 60 mg (6,000 I.U. anti-Xa) in 0.6 mL pre-filled syringe	Injection	Exarane Safety-Lock	JO	MP NP	C4910	P4910	20	3	10

[20] Schedule 1, Part 1, after entry for Enoxaparin in the form Injection containing enoxaparin sodium 80 mg (8,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe *[Brand: Exarane; Maximum Quantity: 20; Number of Repeats: 3]*

insert:

Enoxaparin	Injection containing enoxaparin sodium 80 mg (8,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe	Injection	Exarane Safety-Lock	JO	MP MW NP	C16261	P16261	10	1	10
Enoxaparin	Injection containing enoxaparin sodium 80 mg (8,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe	Injection	Exarane Safety-Lock	JO	MP NP	C4910	P4910	20	3	10

[21] Schedule 1, Part 1, after entry for Enoxaparin in the form Injection containing enoxaparin sodium 100 mg (10,000 I.U. anti-Xa) in 1 mL pre-filled syringe *[Brand: Exarane; Maximum Quantity: 20; Number of Repeats: 3]*

insert:

Enoxaparin	Injection containing enoxaparin sodium 100 mg (10,000 I.U. anti-Xa) in 1 mL pre-filled syringe	Injection	Exarane Safety-Lock	JO	MP MW NP	C16261	P16261	10	1	10
Enoxaparin	Injection containing enoxaparin sodium 100 mg (10,000 I.U. anti-Xa) in 1 mL pre-filled syringe	Injection	Exarane Safety-Lock	JO	MP NP	C4910	P4910	20	3	10

[22] Schedule 1, Part 1, after entry for Enoxaparin in the form Injection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe *[Brand: Exarane Forte; Maximum Quantity: 10; Number of Repeats: 3]*

insert:

Enoxaparin	Injection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe	Injection	Exarane Forte Safety-Lock	JO	MP MW NP	C16261	P16261	10	1	10
Enoxaparin	Injection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe	Injection	Exarane Forte Safety-Lock	JO	MP NP	C4910	P4910	10	3	10

[23] Schedule 1, Part 1, after entry for Enoxaparin in the form Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre-filled syringe *[Brand: Exarane Forte; Maximum Quantity: 10; Number of Repeats: 3]*

insert:

Enoxaparin	Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre-filled syringe	Injection	Exarane Forte Safety-Lock	JO	MP MW NP	C16261	P16261	10	1	10
Enoxaparin	Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre-filled syringe	Injection	Exarane Forte Safety-Lock	JO	MP NP	C4910	P4910	10	3	10

[24] Schedule 1, Part 1, entries for Entecavir in the form Tablet 1 mg (as monohydrate)

omit:

Entecavir	Tablet 1 mg (as monohydrate)	Oral	Entecavir Mylan	AF	MP NP	C5037 C5044		60	5	30	D(100)

[25] Schedule 1, Part 1, after entry for Erlotinib in the form Tablet 100 mg (as hydrochloride) *[Brand: Erlotinib APOTEX]*

insert:

Erlotinib	Tablet 100 mg (as hydrochloride)	Oral	ERLOTINIB ARX	XT	MP	C4473 C4600 C7446		30	3	30	

[26] Schedule 1, Part 1, after entry for Estradiol in the form Tablet containing estradiol valerate 2 mg *[Maximum Quantity: 112; Number of Repeats: 2]*

insert:

Estradiol	Transdermal gel (pump pack) 750 micrograms (as hemihydrate) per 1.25 g dose, 64 doses	Transdermal	Estrogel	HB	MP NP		1	5	1
Estradiol	Transdermal gel (pump pack) 750 micrograms (as hemihydrate) per 1.25 g dose, 64 doses	Transdermal	Estrogel	HB	MP NP	P14238	2	5	1

[27] Schedule 1, Part 1, entries for Estradiol in the form Transdermal patches 1.17 mg, 8

omit:

Estradiol	Transdermal patches 1.17 mg, 8	Transdermal	Estradiol Transdermal System (Sandoz, USA)	HX	MP NP		1	5	1

[28] Schedule 1, Part 1, after entry for Estradiol in the form Transdermal patches 1.56 mg, 8 *[Brand: Estradot 100]*

insert:

Estradiol	Transdermal patches 1.56 mg, 24 (Sandoz) (S19A)	Transdermal	Estramon (Germany, Sandoz)	SZ	MP NP		1	1	1

[29] Schedule 1, Part 1, after entry for Estradiol with norethisterone in the form Transdermal patches containing 510 micrograms estradiol (as hemihydrate) with 4.8 mg norethisterone acetate, 8 *[Maximum Quantity: 2; Number of Repeats: 5]*

insert:

Estradiol with norethisterone	Transdermal patches containing 510 micrograms estradiol (as hemihydrate) with 4.8 mg norethisterone acetate, 8 (S19A)	Transdermal	ESTALIS 250/50 (Canada)	DZ	MP NP		1	5	1
Estradiol with norethisterone	Transdermal patches containing 510 micrograms estradiol (as hemihydrate) with 4.8 mg norethisterone acetate, 8 (S19A)	Transdermal	ESTALIS 250/50 (Canada)	DZ	MP NP	P14238	2	5	1

[30] Schedule 1, Part 1, after entry for Estradiol with norethisterone in the form Transdermal patches containing 620 micrograms estradiol (as hemihydrate) with 2.7 mg norethisterone acetate, 8 *[Maximum Quantity: 2; Number of Repeats: 5]*

insert:

Estradiol with norethisterone	Transdermal patches containing 620 micrograms estradiol (as hemihydrate) with 2.7 mg norethisterone acetate, 8 (S19A)	Transdermal	ESTALIS 140/50 (Canada)	DZ	MP NP		1	5	1
Estradiol with norethisterone	Transdermal patches containing 620 micrograms estradiol (as hemihydrate) with 2.7 mg norethisterone acetate, 8 (S19A)	Transdermal	ESTALIS 140/50 (Canada)	DZ	MP NP	P14238	2	5	1

[31] Schedule 1, Part 1, entry for Ethosuximide in the form Capsule 250 mg

omit from the column headed "Brand": Zarontin *substitute:* ZARONTIN

[32] Schedule 1, Part 1, entry for Evolocumab in the form Injection 140 mg in 1 mL single use pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed "Authorised Prescriber": MP *substitute:* MP NP

(b) omit from the column headed "Circumstances": C15177 C15201 C15395 C15410 *substitute:* C16294 C16336 C16350 C16351

(c) omit from the column headed "Purposes": P15177 P15201 P15395 P15410 *substitute:* P16294 P16336 P16350 P16351

[33] Schedule 1, Part 1, after entry for Ezetimibe and rosuvastatin in the form Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 10 mg (as calcium) *[Brand: Ezalo Composite Pack 10mg+10mg; Maximum Quantity: 2; Number of Repeats: 5]*

insert:

Ezetimibe and rosuvastatin	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 10 mg (as calcium)	Oral	Ezetimibe - Rosuvastatin Sandoz 10 mg/10 mg	SZ	MP NP		1	5	1
Ezetimibe and rosuvastatin	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 10 mg (as calcium)	Oral	Ezetimibe - Rosuvastatin Sandoz 10 mg/10 mg	SZ	MP NP	P14238	2	5	1

[34] Schedule 1, Part 1, after entry for Ezetimibe and rosuvastatin in the form Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 20 mg (as calcium) *[Brand: Ezalo Composite Pack 10mg+20mg; Maximum Quantity: 2; Number of Repeats: 5]*

insert:

Ezetimibe and rosuvastatin	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 20 mg (as calcium)	Oral	Ezetimibe - Rosuvastatin Sandoz 10 mg/20 mg	SZ	MP NP		1	5	1
Ezetimibe and rosuvastatin	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 20 mg (as calcium)	Oral	Ezetimibe - Rosuvastatin Sandoz 10 mg/20 mg	SZ	MP NP	P14238	2	5	1

[35] Schedule 1, Part 1, after entry for Ezetimibe and rosuvastatin in the form Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 40 mg (as calcium) *[Brand: Ezalo Composite Pack 10mg+40mg; Maximum Quantity: 2; Number of Repeats: 5]*

insert:

Ezetimibe and rosuvastatin	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 40 mg (as calcium)	Oral	Ezetimibe - Rosuvastatin Sandoz 10 mg/40 mg	SZ	MP NP		1	5	1
Ezetimibe and rosuvastatin	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 40 mg (as calcium)	Oral	Ezetimibe - Rosuvastatin Sandoz 10 mg/40 mg	SZ	MP NP	P14238	2	5	1

[36] Schedule 1, Part 1, after entry for Ezetimibe and rosuvastatin in the form Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 5 mg (as calcium) *[Brand: Ezalo Composite Pack 10mg+5mg; Maximum Quantity: 2; Number of Repeats: 5]*

insert:

Ezetimibe and rosuvastatin	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 5 mg (as calcium)	Oral	Ezetimibe - Rosuvastatin Sandoz 10 mg/5 mg	SZ	MP NP		1	5	1
Ezetimibe and rosuvastatin	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 5 mg	Oral	Ezetimibe - Rosuvastatin Sandoz	SZ	MP NP	P14238	2	5	1

	(as calcium)	10 mg/5 mg

[37] Schedule 1, Part 1, entry for Faricimab in the form Solution for intravitreal injection 28.8 mg in 0.24 mL (120 mg per mL) *[Maximum Quantity: 1; Number of Repeats: 2]*

(a) insert in numerical order in the column headed "Circumstances": C13336 C13387

(b) insert in numerical order in the column headed "Circumstances": C16309 C16319

(c) insert in numerical order in the column headed "Purposes": P13336 P13387

(d) insert in numerical order in the column headed "Purposes": P16309 P16319

[38] Schedule 1, Part 1, entries for Fingolimod

substitute:

Fingolimod	Capsule 250 micrograms (as hydrochloride)	Oral	Gilenya	NV	MP NP	C16325 C16346	28	5	28
Fingolimod	Capsule 500 micrograms (as hydrochloride)	Oral	AKM Fingolimod	RW	MP NP	C16301 C16323	28	5	28
Fingolimod	Capsule 500 micrograms (as hydrochloride)	Oral	Fingolimod Sandoz	SZ	MP NP	C16301 C16323	28	5	28
Fingolimod	Capsule 500 micrograms (as hydrochloride)	Oral	Fingolimod SUN	RA	MP NP	C16301 C16323	28	5	28
Fingolimod	Capsule 500 micrograms (as hydrochloride)	Oral	Fingolimod-Teva	TB	MP NP	C16301 C16323	28	5	28
Fingolimod	Capsule 500 micrograms (as hydrochloride)	Oral	Fynod	AF	MP NP	C16301 C16323	28	5	28
Fingolimod	Capsule 500 micrograms (as hydrochloride)	Oral	Gilenya	NV	MP NP	C16301 C16323	28	5	28
Fingolimod	Capsule 500 micrograms (as hydrochloride)	Oral	Pharmacor Fingolimod	CR	MP NP	C16301 C16323	28	5	28

[39] Schedule 1, Part 1, entry for Fluoxetine in the form Tablet, dispersible, 20 mg (as hydrochloride)

substitute:

Fluoxetine	Tablet, dispersible, 20 mg (as hydrochloride)	Oral	Zactin Tablet	AF	MP NP	C4755 C6277	P4755 P6277	28	5	28
Fluoxetine	Tablet, dispersible, 20 mg (as hydrochloride)	Oral	Zactin Tablet	AF	MP NP	C15582 C15666	P15582 P15666	56	2	28

[40] Schedule 1, Part 1, entries for Glatiramer

(a) omit from the column headed "Authorised Prescriber" (all instances): MP *substitute (all instances):* MP NP

(b) omit from the column headed "Circumstances" (all instances): C6860 C7695 *substitute (all instances):*C16297 C16321

[41] Schedule 1, Part 1, entries for Gliclazide in the form Tablet 30 mg (modified release)

substitute:

Gliclazide	Tablet 30 mg (modified release)	Oral	APO-Gliclazide MR	TX	MP NP			100	5	100
Gliclazide	Tablet 30 mg (modified release)	Oral	APO-Gliclazide MR	TX	MP NP		P14238	200	5	100
Gliclazide	Tablet 30 mg (modified release)	Oral	Gliclazide MR Viatris	AL	MP NP			100	5	100
Gliclazide	Tablet 30 mg (modified release)	Oral	Gliclazide MR Viatris	AL	MP NP		P14238	200	5	100
Gliclazide	Tablet 30 mg (modified release)	Oral	Glyade MR	AF	MP NP			100	5	100
Gliclazide	Tablet 30 mg (modified release)	Oral	Glyade MR	AF	MP NP		P14238	200	5	100
Gliclazide	Tablet 30 mg (modified release)	Oral	Pharmacor Gliclazide MR	CR	MP NP			100	5	100
Gliclazide	Tablet 30 mg (modified release)	Oral	Pharmacor Gliclazide MR	CR	MP NP		P14238	200	5	100

[42] Schedule 1, Part 1, entry for Inclisiran in the form Injection 284 mg in 1.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 0]*

(a) omit from the column headed "Authorised Prescriber": MP *substitute:* MP NP

(b) *omit from the column headed "Circumstances":* C15065 C15110 C15338 C15369 *substitute:* C16312 C16320 C16352 C16356

(c) *omit from the column headed "Purposes":* P15065 P15110 P15338 P15369 *substitute:* P16312 P16320 P16352 P16356

[43] Schedule 1, Part 1, entry for Inclisiran in the form Injection 284 mg in 1.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 1]*

(a) *omit from the column headed "Authorised Prescriber":* MP *substitute:* MP NP

(b) *omit from the column headed "Circumstances":* C15430 C15443 *substitute:* C16295 C16331

(c) *omit from the column headed "Purposes":* P15430 P15443 *substitute:* P16295 P16331

[44] Schedule 1, Part 1, entries for Insulin isophane in the form Injections (human), cartridges, 100 units per mL, 3 mL, 5

omit:

Insulin isophane	Injections (human), cartridges, 100 units per mL, 3 mL, 5	Injection	Protaphane InnoLet	NI	MP NP		5	1	1

[45] Schedule 1, Part 1, entry for Interferon beta-1b

(a) *omit from the column headed "Authorised Prescriber":* MP *substitute:* MP NP

(b) *omit from the column headed "Circumstances":* C6860 C7695 *substitute:* C16297 C16321

[46] Schedule 1, Part 1, entries for Irbesartan in the form Tablet 75 mg

omit:

Irbesartan	Tablet 75 mg	Oral	Irbesartan GH	GQ	MP NP		30	5	30
Irbesartan	Tablet 75 mg	Oral	Irbesartan GH	GQ	MP NP	P14238	60	5	30

[47] Schedule 1, Part 1, entries for Irbesartan in the form Tablet 150 mg

omit:

Irbesartan	Tablet 150 mg	Oral	Irbesartan GH	GQ	MP NP		30	5	30
Irbesartan	Tablet 150 mg	Oral	Irbesartan GH	GQ	MP NP	P14238	60	5	30

[48] Schedule 1, Part 1, entries for Irbesartan in the form Tablet 300 mg

omit:

Irbesartan	Tablet 300 mg	Oral	Irbesartan GH	GQ	MP NP			30	5	30	
Irbesartan	Tablet 300 mg	Oral	Irbesartan GH	GQ	MP NP		P14238	60	5	30	

[49] Schedule 1, Part 1, after entry for Lenalidomide in the form Capsule 20 mg *[Pack Quantity: 21]*

insert:

Lenalidomide	Capsule 20 mg	Oral	Lenalidomide Sandoz	SZ	MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)

[50] Schedule 1, Part 1, after entry for Metformin in the form Tablet (extended release) containing metformin hydrochloride 500 mg *[Brand: Metex XR; Maximum Quantity: 240; Number of Repeats: 5]*

insert:

Metformin	Tablet (extended release) containing metformin hydrochloride 500 mg	Oral	Metformin Sandoz XR	SZ	MP MW NP	C16261	P16261	120	5	120
Metformin	Tablet (extended release) containing metformin hydrochloride 500 mg	Oral	Metformin Sandoz XR	SZ	MP NP	C14238	P14238	240	5	120

[51] Schedule 1, Part 1, after entry for Metformin in the form Tablet (extended release) containing metformin hydrochloride 1 g *[Brand: METEX XR; Maximum Quantity: 120; Number of Repeats: 5]*

insert:

Metformin	Tablet (extended release) containing metformin hydrochloride 1 g	Oral	Metformin Sandoz XR	SZ	MP MW NP	C16261	P16261	60	5	60
Metformin	Tablet (extended release) containing metformin hydrochloride 1 g	Oral	Metformin Sandoz XR	SZ	MP NP	C14238	P14238	120	5	60

[52] Schedule 1, Part 1, entries for Modafinil

omit:

Modafinil	Tablet 100 mg	Oral	Modafinil Mylan	AF	MP	C10935 C10968 C10970	120	5	60

[53] Schedule 1, Part 1, entry for Mycobacterium bovis (Bacillus Calmette and Guerin), Tice strain

omit from the column headed "Form": Vial containing powder for intravesical administration approximately 5 x 10{SUP}8{/SUP} CFU

substitute: Vial containing powder for intravesical administration approximately 500 million CFU

[54] Schedule 1, Part 1, entries for Nicotine in each of the forms: Transdermal patch 17.5 mg; and Transdermal patch 35 mg

omit from the column headed "Responsible Person": ON *substitute:* UI

[55] Schedule 1, Part 1, entry for Nicotine in the form Transdermal patch 52.5 mg

omit from the column headed "Responsible Person": ON *substitute:* UI

[56] Schedule 1, Part 1, entry for Ofatumumab in the form Solution for injection 20 mg in 0.4 mL pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 5]*

(a) omit from the column headed "Authorised Prescriber": MP *substitute:* MP NP

(b) omit from the column headed "Circumstances": C10172 *substitute:* C16301

(c) omit from the column headed "Purposes": P10172 *substitute:* P16301

[57] Schedule 1, Part 1, entry for Ofatumumab in the form Solution for injection 20 mg in 0.4 mL pre-filled pen *[Maximum Quantity: 3; Number of Repeats: 0]*

(a) omit from the column headed "Authorised Prescriber": MP *substitute:* MP NP

(b) omit from the column headed "Circumstances": C10162 *substitute:* C16323

(c) omit from the column headed "Purposes": P10162 *substitute:* P16323

[58] Schedule 1, Part 1, entries for Olanzapine in the form Tablet 10 mg (orally disintegrating)

omit:

Olanzapine	Tablet 10 mg (orally disintegrating)	Oral	Olanzapine ODT generichealth 10	GQ	MP NP	C4246 C5869	28	5	28

[59] Schedule 1, Part 1, after entry for Opicapone

insert:

Osilodrostat	Tablet 1 mg (as phosphate)	Oral	Isturisa	RJ	MP	C16317	P16317	60	5	60
Osilodrostat	Tablet 1 mg (as phosphate)	Oral	Isturisa	RJ	MP	C16306 C16349	P16306 P16349	60	6	60
Osilodrostat	Tablet 5 mg (as phosphate)	Oral	Isturisa	RJ	MP	C16317	P16317	60	5	60
Osilodrostat	Tablet 5 mg (as phosphate)	Oral	Isturisa	RJ	MP	C16306 C16349	P16306 P16349	60	6	60

[60] Schedule 1, Part 1, entries for Ozanimod

substitute:

Ozanimod	Capsule 920 micrograms	Oral	Zeposia	BQ	MP	C13995 C14003 C14004 C14005	P13995 P14003 P14004 P14005	28	3	28
Ozanimod	Capsule 920 micrograms	Oral	Zeposia	BQ	MP NP	C16301 C16323	P16301 P16323	28	5	28
Ozanimod	Capsule 920 micrograms	Oral	Zeposia	BQ	MP	C13946 C14002	P13946 P14002	28	5	28
Ozanimod	Pack containing 4 capsules 230 micrograms and 3 capsules 460 micrograms	Oral	Zeposia	BQ	MP NP	C16301 C16323		1	0	1
Ozanimod	Pack containing 4 capsules 230 micrograms and 3 capsules 460 micrograms	Oral	Zeposia	BQ	MP	C14017		1	0	1

[61] Schedule 1, Part 1, entry for Peginterferon beta-1a in the form Pack containing single use injection pens containing 63 micrograms in 0.5 mL and 94 micrograms in 0.5 mL

(a) omit from the column headed "Authorised Prescriber": MP *substitute:* MP NP

(b) omit from the column headed "Circumstances": C7695 *substitute:* C16321

[62] Schedule 1, Part 1, entry for Peginterferon beta-1a in the form Single use injection pen containing 125 micrograms in 0.5 mL *[Maximum Quantity: 2; Number of Repeats: 4]*

(a) omit from the column headed "Authorised Prescriber": MP *substitute:* MP NP

(b) omit from the column headed "Circumstances": C7695 *substitute:* C16321

(c) omit from the column headed "Purposes": P7695 *substitute:* P16321

[63] Schedule 1, Part 1, entry for Peginterferon beta-1a in the form Single use injection pen containing 125 micrograms in 0.5 mL *[Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed "Authorised Prescriber": MP *substitute:* MP NP

(b) omit from the column headed "Circumstances": C6860 *substitute:* C16297

(c) omit from the column headed "Purposes": P6860 *substitute:* P16297

[64] Schedule 1, Part 1, entry for Permethrin in the form Cream 50 mg per g, 30 g

omit from the column headed "Responsible Person": ON *substitute:* UI

[65] Schedule 1, Part 1, entries for Pirfenidone in the form Tablet 801mg

omit from the column headed "Form" (all instances): Tablet 801mg *substitute (all instances):* Tablet 801 mg

[66] Schedule 1, Part 1, entries for Pregabalin in the form Capsule 150 mg

omit:

Pregabalin	Capsule 150 mg	Oral	Cipla Pregabalin	LR	MP NP	C4172	56	5	56

[67] Schedule 1, Part 1, after entry for Prochlorperazine in the form Tablet containing prochlorperazine maleate 5 mg *[Brand: Stemetil]*

insert:

Progesterone	Capsule 100 mg	Oral	Prometrium	HB	MP NP		30	5	30
Progesterone	Capsule 100 mg	Oral	Prometrium	HB	MP NP	P14238	60	5	30

[68] Schedule 1, Part 1, after entry for Progesterone in the form Vaginal tablet 100 mg

insert:

Progesterone and estradiol	Pack containing 30 capsules progesterone 100 mg (micronised) and transdermal gel (pump pack) estradiol 750 micrograms (as hemihydrate) per 1.25 g	Oral/transdermal	Estrogel Pro	HB	MP NP		1	5	1

	dose, 64 doses									
Progesterone and estradiol	Pack containing 30 capsules progesterone 100 mg (micronised) and transdermal gel (pump pack) estradiol 750 micrograms (as hemihydrate) per 1.25 g dose, 64 doses	Oral/trans dermal	Estrogel Pro	HB	MP NP		P14238	2	5	1

[69] Schedule 1, Part 1, entries for Quetiapine in the form Tablet 100 mg (as fumarate)

omit:

Quetiapine	Tablet 100 mg (as fumarate)	Oral	Quetiapine APOTEX	GX	MP NP	C4246 C5611 C5869		90	5	90

[70] Schedule 1, Part 1, entries for Quinapril in the form Tablet 5 mg (as hydrochloride)

omit:

Quinapril	Tablet 5 mg (as hydrochloride)	Oral	Accupril	PF	MP NP			30	5	30

[71] Schedule 1, Part 1, entries for Ramipril in the form Tablet 1.25 mg

omit:

Ramipril	Tablet 1.25 mg	Oral	Tryzan Tabs 1.25	AF	MP NP			30	5	30
Ramipril	Tablet 1.25 mg	Oral	Tryzan Tabs 1.25	AF	MP NP		P14238	60	5	30

[72] Schedule 1, Part 1, entries for Ramipril in the form Tablet 2.5 mg

omit:

Ramipril	Tablet 2.5 mg	Oral	Tryzan Tabs 2.5	AF	MP NP			30	5	30
Ramipril	Tablet 2.5 mg	Oral	Tryzan Tabs 2.5	AF	MP NP		P14238	60	5	30

[73] Schedule 1, Part 1, entries for Ramipril in the form Tablet 5 mg

omit:

Ramipril	Tablet 5 mg	Oral	Tryzan Tabs 5	AF	MP NP		30	5	30
Ramipril	Tablet 5 mg	Oral	Tryzan Tabs 5	AF	MP NP	P14238	60	5	30

[74] Schedule 1, Part 1, entries for Ramipril in the form Tablet 10 mg

omit:

Ramipril	Tablet 10 mg	Oral	Tryzan Tabs 10	AF	MP NP		30	5	30
Ramipril	Tablet 10 mg	Oral	Tryzan Tabs 10	AF	MP NP	P14238	60	5	30

[75] Schedule 1, Part 1, entry for Risankizumab in the form Injection 150 mg in 1 mL pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 1]*

(a) *insert in numerical order in the column headed "Circumstances":* C15902 C15903 C16348

(b) *insert in numerical order in the column headed "Purposes":* P15902 P15903 P16348

[76] Schedule 1, Part 1, entry for Risankizumab in the form Injection 150 mg in 1 mL pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 2]*

(a) *insert in numerical order in the column headed "Circumstances":* C16305 C16338 C16339 C16340

(b) *insert in numerical order in the column headed "Purposes":* P16305 P16338 P16339 P16340

[77] Schedule 1, Part 1, entries for Siponimod

substitute:

Siponimod	Tablet 250 micrograms (as hemifumarate)	Oral	Mayzent	NV	MP NP	C16303 C16347 P16303 P16347	12	0	12
Siponimod	Tablet 250 micrograms (as hemifumarate)	Oral	Mayzent	NV	MP NP	C16303 C16347 P16303 P16347	120	5	120
Siponimod	Tablet 1 mg (as	Oral	Mayzent	NV	MP	C16303 C16347	28	5	28

	hemifumarate)				NP				
Siponimod	Tablet 2 mg (as hemifumarate)	Oral	Mayzent	NV	MP NP	C16303 C16347	28	5	28

[78] Schedule 1, Part 1, entries for Sumatriptan

omit:

Sumatriptan	Nasal spray 20 mg in 0.1 mL single dose unit	Nasal	Imigran	AS	MP NP	C5259	2	5	2

[79] Schedule 1, Part 1, entries for Tenecteplase

omit:

Tenecteplase	Powder for injection 40 mg with solvent	Injection	Metalyse	BY	MP NP	C5783	1	0	1

[80] Schedule 1, Part 1, entries for Teriflunomide

(a) omit from the column headed "Authorised Prescriber" (all instances): MP *substitute (all instances):* MP NP

(b) omit from the column headed "Circumstances" (all instances): C10150 C10199 *substitute (all instances):* C16315 C16323

[81] Schedule 1, Part 1, entries for Timolol

omit:

Timolol	Eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL (S19A)	Application to the eye	Timoptol XE 0.50% (South Africa)	LM	MP AO		1	5	1

[82] Schedule 1, Part 1, after entry for Ursodeoxycholic acid in the form Capsule 250 mg *[Brand: Ursosan]*

insert:

Ursodeoxycholic acid	Capsule 500 mg	Oral	Ursodox GH	GQ	MP NP	C9032	100	4	100

[83] Schedule 1, Part 2, omit entry for Budesonide with formoterol

[84] Schedule 1, Part 2, omit entry for Triglycerides, long chain with glucose polymer

[85] **Schedule 3,**

omit:

NI	Novo Nordisk Pharmaceuticals Pty. Limited	40 002 879 996

[86] **Schedule 3, after entry for Responsible Person code UC**

insert:

UI	PERRIGO AUSTRALIA PTY LIMITED	15 141 623 403

[87] **Schedule 4, Part 1, omit entry for Circumstances Code "C6860"**

[88] **Schedule 4, Part 1, omit entry for Circumstances Code "C7695"**

[89] **Schedule 4, Part 1, omit entry for Circumstances Code "C10093"**

[90] **Schedule 4, Part 1, omit entry for Circumstances Code "C10139"**

[91] **Schedule 4, Part 1, omit entry for Circumstances Code "C10140"**

[92] **Schedule 4, Part 1, omit entry for Circumstances Code "C10150"**

[93] **Schedule 4, Part 1, omit entry for Circumstances Code "C10162"**

[94] **Schedule 4, Part 1, omit entry for Circumstances Code "P10170"**

[95] **Schedule 4, Part 1, omit entry for Circumstances Code "C10171"**

[96] **Schedule 4, Part 1, omit entry for Circumstances Code "C10172"**

[97] **Schedule 4, Part 1, omit entry for Circumstances Code "C10198"**

[98] **Schedule 4, Part 1, omit entry for Circumstances Code "C10199"**

[99] **Schedule 4, Part 1, omit entry for Circumstances Code "C10953"**

[100] **Schedule 4, Part 1, omit entry for Circumstances Code "C10955"**

[101] **Schedule 4, Part 1, omit entry for Circumstances Code "C13034"**

[102] **Schedule 4, Part 1, omit entry for Circumstances Code "C13072"**

[103] Schedule 4, Part 1, entry for Circumstances Code "C13336"

insert in alphabetical order in the column headed "Listed Drug": Faricimab

[104] Schedule 4, Part 1, entry for Circumstances Code "C13387"

insert in alphabetical order in the column headed "Listed Drug": Faricimab

[105] Schedule 4, Part 1, entry for Circumstances Code "C14238"

(a) insert in alphabetical order in the column headed "Listed Drug": Progesterone

(b) insert in alphabetical order in the column headed "Listed Drug": Progesterone and estradiol

[106] Schedule 4, Part 1, omit entry for Circumstances Code "C14587"

[107] Schedule 4, Part 1, omit entry for Circumstances Code "C14588"

[108] Schedule 4, Part 1, omit entry for Circumstances Code "C14631"

[109] Schedule 4, Part 1, omit entry for Circumstances Code "C15065"

[110] Schedule 4, Part 1, omit entry for Circumstances Code "C15110"

[111] Schedule 4, Part 1, omit entry for Circumstances Code "C15177"

[112] Schedule 4, Part 1, omit entry for Circumstances Code "C15201"

[113] Schedule 4, Part 1, omit entry for Circumstances Code "C15338"

[114] Schedule 4, Part 1, omit entry for Circumstances Code "C15369"

[115] Schedule 4, Part 1, omit entry for Circumstances Code "C15395"

[116] Schedule 4, Part 1, omit entry for Circumstances Code "C15410"

[117] Schedule 4, Part 1, omit entry for Circumstances Code "C15430"

[118] Schedule 4, Part 1, omit entry for Circumstances Code "C15443"

[119] Schedule 4, Part 1, entry for Circumstances Code "C15553"

insert in alphabetical order in the column headed "Listed Drug": Duloxetine

[120] Schedule 4, Part 1, entry for Circumstances Code "C15902"

insert in alphabetical order in the column headed "Listed Drug": Risankizumab

[121] Schedule 4, Part 1, entry for Circumstances Code "C15903"

insert in alphabetical order in the column headed "Listed Drug": Risankizumab

[122] Schedule 4, Part 1, after entry for Circumstances Code "C16290"

insert:

C16292	P16292	CN16292	Blinatumomab	Acute lymphoblastic leukaemia Induction treatment The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less; AND The condition must not be present in the central nervous system or testis; AND Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive; AND Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy; AND Patient must not have received more than 1 line of salvage therapy; AND The condition must be one of the following: (i) untreated with this drug for Precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL), (ii) treated with this drug for Pre-B-cell ALL, but the condition has not relapsed within 6 months of completing that course of treatment; AND The condition must have more than 5% blasts in bone marrow; AND The treatment must not be more than 2 treatment cycles under this restriction in a lifetime. According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 9 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for 4 or more hours), supervision by a health care professional or hospitalisation is recommended. An amount of 651 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 1. An amount of 784 microgram, which may be obtained under Induction treatment - balance of supply restriction, will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 2. Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. The authority application must be made in writing and must include:	Compliance with Written Authority Required procedures

				(1) details of the proposed prescription; and (2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and (3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and (4) if applicable, the date of completion of blinatumomab treatment for Pre-B-cell ALL in CR and the date of the patient's subsequent relapse; and (5) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application.	
C16294	P16294	CN16294	Evolocumab	Familial heterozygous hypercholesterolaemia Initial treatment The treatment must be in conjunction with dietary therapy and exercise; AND The condition must have been confirmed by genetic testing; OR The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6; AND Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; OR Patient must have an LDL cholesterol level in excess of 5 millimoles per litre; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; AND Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9), (ii) inclisiran, for this PBS indication. Must be treated by a specialist physician; OR Must be treated by an authorised prescriber in consultation with a specialist physician.	Compliance with Authority Required procedures - Streamlined Authority Code 16294

	Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be documented in the patient's medical records and must be no more than 8 weeks old. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal. In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved. The following must be documented in the patient's medical records:

				(i) the qualifying Dutch Lipid Clinic Network Score; or (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia One of the following must be documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.	
C16295	P16295	CN16295	Inclisiran	Familial heterozygous hypercholesterolaemia Initial treatment The treatment must be in conjunction with dietary therapy and exercise; AND The condition must have been confirmed by genetic testing; OR The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6; AND Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; OR Patient must have an LDL cholesterol level in excess of 5 millimoles per litre; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; AND	Compliance with Authority Required procedures - Streamlined Authority Code 16295

	Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication. Must be treated by a specialist physician; OR Must be treated by an authorised prescriber in consultation with a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be documented in the patient's medical records and must be no more than 8 weeks old. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.	

				In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved. The following must be documented in the patient's medical records: (i) the qualifying Dutch Lipid Clinic Network Score; or (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia One of the following must be documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.	
C16297	P16297	CN16297	Glatiramer Interferon beta-1b Peginterferon beta-1a	Multiple sclerosis Continuing treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis; 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; AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy. Must be treated by a medical practitioner; OR Must be treated by a nurse practitioner in consultation with a specialist physician.	Compliance with Authority Required procedures - Streamlined Authority Code 16297
C16299	P16299	CN16299	Cladribine	Relapsing remitting 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; AND	Compliance with Authority Required procedures - Streamlined Authority Code 16299

				The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not show continuing progression of disability while on treatment with this drug; AND Patient must have demonstrated compliance with, and an ability to tolerate, this therapy. Must be treated by a medical practitioner; OR Must be treated by a nurse practitioner in consultation with a specialist physician. The prescriber should request authority approval for the appropriate combination of packs (1, 4 or 6 tablets) to provide sufficient drug for a treatment week based on the weight of the patient in accordance with the TGA approved Product Information. Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1.	
C16301	P16301	CN16301	Fingolimod Ofatumumab Ozanimod	Multiple sclerosis Continuing treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not show continuing progression of disability while on treatment with this drug; AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy. Must be treated by a medical practitioner; OR Must be treated by a nurse practitioner in consultation with a specialist physician.	Compliance with Authority Required procedures - Streamlined Authority Code 16301
C16303	P16303	CN16303	Siponimod	Multiple sclerosis Continuing treatment (including recommencement of treatment) The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority Code 16303

				Patient must not show continuing progression of disability while on treatment with this drug; AND Patient must be ambulatory, with/without assistance/support; AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy. Must be treated by a medical practitioner; OR Must be treated by a nurse practitioner in consultation with a specialist physician.	
C16305	P16305	CN16305	Risankizumab	Severe psoriatic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 28 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must be at least 18 years of age. 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:	Compliance with Written Authority Required procedures

				(1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. 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.	
C16306	P16306	CN16306	Osilodrostat	Endogenous Cushing's syndrome Initial treatment The condition must be at least one of: (i) persistent hypercortisolism after surgery, (ii) recurrent hypercortisolism after surgery, (iii) inappropriate for surgery; AND Patient must have active endogenous Cushing's Syndrome determined by a mean urinary free cortisol (UFC) level greater than 1.3 times the upper limit of normal (ULN); OR Patient must have undergone treatment for this condition with conventional therapies to control cortisol production resulting in an improved UFC level prior to applying for the initial authority application of this drug. Must be treated by an endocrinologist.	Compliance with Authority Required procedures

				Patient must be at least 18 years of age. For the purposes of administering this restriction, the mean UFC is the average of at least two values being 1.3 times greater than the ULN. Patient must undergo a dose titration period whereby responses must be assessed every 1-2 weeks until the mean UFC levels are within the normal range. At the time of authority application, medical practitioners must request the appropriate number of packs to provide sufficient drug, based on the prescribed dose of the patient, for 4 weeks of treatment. A separate authority prescription form must be completed for each strength requested. The dose must not exceed 30 mg twice daily. Up to a maximum of 6 repeats will be authorised. Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the dose is changing), mark the prescription that is intended for no further supply as 'Cancelled'. The condition is inappropriate for surgery if the patient: (i) has a medical contraindication for surgery; (ii) has inoperable tumours; (iii) has been determined that surgery is unlikely to reduce hypercortisolism; (iv) refuses surgery; (v) cannot access surgical treatment.	
C16308	P16308	CN16308	Blinatumomab	Precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL) Continuing treatment of Pre-B-cell ALL in complete haematological remission (CR) Must be treated by a physician experienced in the treatment of haematological malignancies. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have achieved a complete remission; AND The condition must be negative for measurable residual disease (MRD) using the same method used to establish initial MRD status; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND The treatment must not be more than 2 treatment cycles under this restriction in a lifetime. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended.	Compliance with Authority Required procedures

				An amount of 784 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle. Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. 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.	
C16309	P16309	CN16309	Faricimab	Central retinal vein occlusion with macular oedema Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO); AND Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment; AND The condition must be diagnosed by optical coherence tomography; OR The condition must be diagnosed by fluorescein angiography; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. 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). All reports must be documented in the patient's medical records.	Compliance with Written Authority Required procedures
C16312	P16312	CN16312	Inclisiran	Non-familial hypercholesterolaemia 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 April 2024; AND	Compliance with Authority Required procedures - Streamlined Authority Code 16312

		The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have had symptomatic atherosclerotic cardiovascular disease prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had an LDL cholesterol level in excess of 1.8 millimoles per litre prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories) prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had diabetes mellitus with microalbuminuria prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had diabetes mellitus and be aged 60 years of more prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus that was present prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had a Thrombolysis in Myocardial Infarction (TIMI) Risk Score for Secondary Prevention of 4 or higher prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR

	Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; AND Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication. Must be treated by a specialist physician; OR Must be treated by an authorised prescriber in consultation with a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless

	there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal. In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved. One of the following must be documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. One or more of the following must be documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event: (i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or (ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or (iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or (iv) diabetes mellitus with microalbuminuria; or (v) diabetes mellitus and age 60 years or more; or (vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or (vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher. 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. Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.	

C16315	P16315	CN16315	Dimethyl fumarate Diroximel fumarate Teriflunomide	Multiple sclerosis Continuing treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not show continuing progression of disability while on treatment with this drug. Must be treated by a medical practitioner; OR Must be treated by a nurse practitioner in consultation with a specialist physician. 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 16315
C16317	P16317	CN16317	Osilodrostat	Endogenous Cushing's syndrome Continuing treatment Patient must have received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated a complete response after at least 26 weeks of treatment with this drug; OR Patient must have demonstrated a partial response after at least 26 weeks of treatment with this drug. Must be treated by an endocrinologist. Patient must be at least 18 years of age. For the purposes of administering this restriction, a complete response is defined as a mean urinary free cortisol (UFC) level of less than or equal to the upper limit of normal (ULN). A partial response is defined as mean UFC level of greater than ULN but with at least 50% reduction from the baseline value. The mean UFC should be the average of at least two urine samples. At the time of authority application, medical practitioners must request the appropriate number of packs to provide sufficient drug, based on the prescribed dose of the patient, for 4 weeks of treatment.	Compliance with Authority Required procedures

				A separate authority prescription form must be completed for each strength requested. The dose must not exceed 30 mg twice daily. Up to a maximum of 5 repeats will be authorised. Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the dose is changing), mark the prescription that is intended for no further supply as 'Cancelled'. An application for the continuing treatment must be accompanied with the assessment of response conducted after 26 weeks from the first dose of osilodrostat and no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for patients who meet the continuing restriction for PBS-subsidised treatment.	
C16319	P16319	CN16319	Faricimab	Branch retinal vein occlusion with macular oedema Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO); AND Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment; AND The condition must be diagnosed by optical coherence tomography; OR The condition must be diagnosed by fluorescein angiography; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. 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). All reports must be documented in the patient's medical records.	Compliance with Written Authority Required procedures

C16320	P16320	CN16320	Inclisiran	Familial heterozygous hypercholesterolaemia Continuing treatment with this drug or switching treatment from a monoclonal antibody inhibiting proprotein coverase subtilisin kexin type 9 (PSCK9) for this PBS indication Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR Patient must have previously received PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication. Must be treated by a medical practitioner; OR Must be treated by a nurse practitioner in consultation with a specialist physician.	Compliance with Authority Required procedures - Streamlined Authority Code 16320
C16321	P16321	CN16321	Glatiramer Interferon beta-1b Peginterferon beta-1a	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, with 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 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). Must be treated by a medical practitioner; OR Must be treated by a nurse practitioner in consultation with a specialist physician. 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 16321
C16323	P16323	CN16323	Dimethyl fumarate Diroximel fumarate Fingolimod Ofatumumab Ozanimod	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	Compliance with Authority Required procedures - Streamlined Authority Code 16323

			Teriflunomide	magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support). Must be treated by a medical practitioner; OR Must be treated by a nurse practitioner in consultation with a specialist physician. Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.	
C16325	P16325	CN16325	Fingolimod	Multiple sclerosis Initial treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support). Must be treated by a medical practitioner; OR Must be treated by a nurse practitioner in consultation with a specialist physician. Patient must weigh 40 kg or less. 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 16325
C16331	P16331	CN16331	Inclisiran	Non-familial hypercholesterolaemia Initial treatment The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have symptomatic atherosclerotic cardiovascular disease; AND	Compliance with Authority Required procedures - Streamlined Authority Code 16331

	Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre; AND Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); OR Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; OR Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; AND Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication. Must be treated by a specialist physician; OR Must be treated by an authorised prescriber in consultation with a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

One of the following must be documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

				(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. One or more of the following must be documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event: (i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or (ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or (iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or (iv) diabetes mellitus with microalbuminuria; or (v) diabetes mellitus and age 60 years or more; or (vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or (vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher. Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.	
C16334	P16334	CN16334	Blinatumomab	Precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL) Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements for Pre-B-cell ALL in complete haematological remission (CR) Must be treated by a physician experienced in the treatment of haematological malignancies. Patient must have commenced treatment with this medicine for this condition prior to 1 March 2025; AND Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, at initiation of non-PBS-subsidised treatment with this drug; AND The condition must not be present in the central nervous system or testis; AND Patient must have achieved complete remission following intensive combination chemotherapy for initial treatment of acute lymphoblastic leukaemia (ALL) at initiation of non-PBS-subsidised treatment with this drug; OR Patient must have had at initiation of non-PBS-subsidised treatment with this drug: (i) achieved complete remission following intensive combination chemotherapy, (ii) measurable residual disease based on measurement in bone marrow, documented after the last course of systemic chemotherapy given as intensive combination chemotherapy treatment of ALL/as subsequent salvage therapy, whichever was the later, measured using flow cytometry/molecular methods; AND	Compliance with Written Authority Required procedures

				Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND Patient must have received at least 1 treatment cycle of non-PBS therapy under this restriction; AND The treatment must not be more than 4 treatment cycles of therapy (non-PBS and PBS) under this restriction in a lifetime. According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended. An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle. Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed Acute Lymphoblastic Leukaemia in complete haematological remission PBS Authority Application - Supporting Information Form; and (3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy; and (4) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application. 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.	
C16336	P16336	CN16336	Evolocumab	Non-familial hypercholesterolaemia Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR Patient must have received PBS-subsidised treatment for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication.	Compliance with Authority Required procedures - Streamlined Authority Code 16336

				Must be treated by a medical practitioner; OR Must be treated by a nurse practitioner in consultation with a specialist physician.	
C16338	P16338	CN16338	Risankizumab	Severe psoriatic arthritis Initial treatment - Initial 1 (new patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 28 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must be at least 18 years of age. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment	Compliance with Written Authority Required procedures

				with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C16339	P16339	CN16339	Risankizumab	Severe psoriatic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 28 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must be at least 18 years of age.	Compliance with Written Authority Required procedures

	Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	

C16340	P16340	CN16340	Risankizumab	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 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 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
C16341	P16341	CN16341	Blinatumomab	Precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL) Initial treatment of Pre-B-cell ALL in complete haematological remission (CR) Must be treated by a physician experienced in the treatment of haematological malignancies. Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND The condition must not be present in the central nervous system or testis; AND Patient must have achieved complete remission following intensive combination chemotherapy for initial treatment of acute lymphoblastic leukaemia (ALL); OR Patient must have: (i) achieved complete remission following intensive combination chemotherapy, (ii) measurable residual disease based on measurement in bone marrow, documented after the last course of systemic chemotherapy given as intensive combination chemotherapy treatment of ALL/as subsequent salvage therapy, whichever was the later, measured using flow cytometry/molecular methods; AND The treatment must not be more than 2 treatment cycles under this restriction in a lifetime. According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 days of the first cycle and the first 2 days of the second cycle.	Compliance with Written Authority Required procedures

				For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended. An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle. Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed Acute Lymphoblastic Leukaemia in complete haematological remission PBS Authority Application - Supporting Information Form; and (3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy; and (4) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application. 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.	
C16345	P16345	CN16345	Cladribine	Relapsing remitting multiple sclerosis Initial treatment The condition must be diagnosed by a neurologist; AND 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, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support). Must be treated by a medical practitioner; OR Must be treated by a nurse practitioner in consultation with a specialist physician. 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 16345

				The prescriber should write authority prescriptions for the appropriate combination of packs (1, 4 or 6 tablets) to provide sufficient drug for a treatment week based on the weight of the patient in accordance with the TGA approved Product Information. Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1.	
C16346	P16346	CN16346	Fingolimod	Multiple sclerosis Continuing treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not show continuing progression of disability while on treatment with this drug; AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy. Patient must weigh 40 kg or less. Must be treated by a medical practitioner; OR Must be treated by a nurse practitioner in consultation with a specialist physician.	Compliance with Authority Required procedures - Streamlined Authority Code 16346
C16347	P16347	CN16347	Siponimod	Multiple sclerosis Initial treatment The condition must be/have previously been diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of at least one of the brain/spinal cord; OR The condition must be/have previously been diagnosed as clinically definite relapsing-remitting multiple sclerosis supported by written certification, which is documented in the patient's medical records, from a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory, with/without assistance/support; AND Patient must have mild disability in at least 3 functional systems; OR Patient must have moderate disability in at least 1 functional system. Must be treated by a medical practitioner; OR	Compliance with Authority Required procedures - Streamlined Authority Code 16347

				Must be treated by a nurse practitioner in consultation with a specialist physician. Functional systems referred to in this restriction are the: visual, brain stem, pyramidal, cerebellar, sensory, bowel/bladder and cerebral/cognitive systems. Select a dose and pack size appropriate for the patient's CYP2C9 metabolising enzyme status.	
C16348	P16348	CN16348	Risankizumab	Severe psoriatic arthritis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2025; 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 to treatment with this drug for this condition if the patient has received non-PBS-subsidised treatment for at least 12 weeks; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must be at least 18 years of age. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:	Compliance with Written Authority Required procedures

	an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. 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: (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). (c) the date of commencement of this drug; and (d) results of the baseline patient assessment prior to initiation of non-PBS-subsidised therapy with this drug. The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all continuing treatment applications.

				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. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C16349	P16349	CN16349	Osilodrostat	Endogenous Cushing's syndrome Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2025; AND The condition must have been, at least one of: (i) persistent hypercortisolism after surgery, (ii) recurrent hypercortisolism after surgery, (iii) inappropriate for surgery, prior to commencing non-PBS-subsidised treatment with this drug; AND Patient must have had active endogenous Cushing's Syndrome determined by a mean urinary free cortisol (UFC) level greater than 1.3 times the upper limit of normal (ULN) prior to commencing non-PBS-subsidised treatment with this drug; AND Patient must have demonstrated a complete response if they have received at least 26 weeks of initial non-PBS-subsidised therapy; OR Patient must have demonstrated a partial response if they have received at least 26 weeks of initial non-PBS-subsidised therapy. Must be treated by an endocrinologist. Patient must be at least 18 years of age. For the purposes of administering this restriction, a complete response is defined as a mean urinary free cortisol (UFC) level of less than or equal to the upper limit of normal (ULN). A partial response is defined as mean UFC level of greater than ULN but with at least 50% reduction from the baseline value. The mean UFC should be the average of at least two urine samples. Patient must undergo a dose titration period whereby responses must be assessed every 1-2 weeks until the mean UFC levels are within the normal range.	Compliance with Authority Required procedures

				At the time of authority application, medical practitioners must request the appropriate number of packs to provide sufficient drug, based on the prescribed dose of the patient, for 4 weeks of treatment. A separate authority prescription form must be completed for each strength requested. The dose must not exceed 30 mg twice daily. Up to a maximum of 6 repeats will be authorised. Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the dose is changing), mark the prescription that is intended for no further supply as 'Cancelled'. The condition is inappropriate for surgery if the patient: (i) has a medical contraindication for surgery; (ii) has inoperable tumours; (iii) has been determined that surgery is unlikely to reduce hypercortisolism; (iv) refuses surgery; (v) cannot access surgical treatment. An application for the continuing treatment must be accompanied with the assessment of response conducted after 26 weeks from the first dose of osilodrostat and no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for patients who meet the continuing restriction for PBS-subsidised treatment.	
C16350	P16350	CN16350	Evolocumab	Familial heterozygous hypercholesterolaemia Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR Patient must have received PBS-subsidised treatment for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication. Must be treated by a medical practitioner; OR Must be treated by a nurse practitioner in consultation with a specialist physician.	Compliance with Authority Required procedures - Streamlined Authority Code 16350
C16351	P16351	CN16351	Evolocumab	Non-familial hypercholesterolaemia Initial treatment The treatment must be in conjunction with dietary therapy and exercise; AND	Compliance with Authority Required procedures - Streamlined Authority Code 16351

	Patient must have symptomatic atherosclerotic cardiovascular disease; AND
	Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre; AND
	Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); OR
	Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; OR
	Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; OR
	Patient must have diabetes mellitus with microalbuminuria; OR
	Patient must have diabetes mellitus and be aged 60 years or more; OR
	Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
	Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher; AND
	Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
	Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
	Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND
	Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR
	Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; AND
	Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9), (ii) inclisiran, for this PBS indication.
	Must be treated by a specialist physician; OR
	Must be treated by an authorised prescriber in consultation with a specialist physician.
	Symptomatic atherosclerotic cardiovascular disease is defined as:
	(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

One of the following must be documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

				(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. One or more of the following must be documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event: (i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or (ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or (iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or (iv) diabetes mellitus with microalbuminuria; or (v) diabetes mellitus and age 60 years of more; or (vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or (vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.	
C16352	P16352	CN16352	Inclisiran	Familial heterozygous hypercholesterolaemia 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 April 2024; AND The treatment must be in conjunction with dietary therapy and exercise; AND The condition must have been confirmed by genetic testing prior to starting non-PBS-subsidised treatment with this drug for this condition; OR The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6 prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease at the time non-PBS-subsidised treatment with this drug for this condition was initiated; OR Patient must have had an LDL cholesterol level in excess of 5 millimoles per litre at the time non-PBS-subsidised treatment with this drug for this condition was initiated; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least	Compliance with Authority Required procedures - Streamlined Authority Code 16352

12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR

Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR

Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND

Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR

Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; AND

Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

Must be treated by a specialist physician; OR

Must be treated by an authorised prescriber in consultation with a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated.

A clinically important product-related adverse event is defined as follows:

	(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal. In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved. The following must be documented in the patient's medical records: (i) the qualifying Dutch Lipid Clinic Network Score; or (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia One of the following must be documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. 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. Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.	

C16356	P16356	CN16356	Inclisiran	Non-familial hypercholesterolaemia Continuing treatment with this drug or switching treatment from a monoclonal antibody inhibiting proprotein coverase subtilisin kexin type 9 (PSCK9) for this PBS indication Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR Patient must have previously received PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication. Must be treated by a medical practitioner; OR Must be treated by a nurse practitioner in consultation with a specialist physician.	Compliance with Authority Required procedures - Streamlined Authority Code 16356

[123] Schedule 5, entries for Acarbose

substitute:

Acarbose	GRP-29491	Tablet 50 mg	Oral	Acarbose Viatris GLYBOSAY
Acarbose	GRP-29491	Tablet 50 mg (S19A)	Oral	Acarbose 50 mg tablets (Morningside, UK)
Acarbose	GRP-29496	Tablet 100 mg	Oral	Acarbose Viatris GLYBOSAY
Acarbose	GRP-29496	Tablet 100 mg (S19A)	Oral	Acarbose 100 mg tablets (Morningside, UK)

[124] Schedule 5, entry for Adalimumab *[GRP-29151]*

insert in the column headed "Brand" after entry for the Brand "Humira": Hyrimoz

[125] Schedule 5, omit entries for Amoxicillin with clavulanic acid *[GRP-29087]*

[126] Schedule 5, omit entries for Azithromycin *[GRP-29088]*

[127] Schedule 5, omit entry for Betaxolol

[128] Schedule 5, entry for Dutasteride with tamsulosin

insert in the column headed "Brand" after entry for the Brand "Dutasteride/Tamsulosin Lupin 500/400": Dutasteride/Tamsulosin Sandoz 500/400

[129] Schedule 5, entries for Enoxaparin

substitute:

Enoxaparin	GRP-22367	Injection containing enoxaparin sodium 40 mg (4,000 I.U. anti-Xa) in 0.4 mL pre-filled syringe	Injection	Clexane Safety-Lock Exarane Exarane Safety-Lock
Enoxaparin	GRP-22371	Injection containing enoxaparin sodium 60 mg (6,000 I.U. anti-Xa) in 0.6 mL pre-filled syringe	Injection	Clexane Safety-Lock Exarane Exarane Safety-Lock
Enoxaparin	GRP-22357	Injection containing enoxaparin sodium 100 mg (10,000 I.U. anti-Xa) in 1 mL pre-filled syringe	Injection	Clexane Safety-Lock Exarane Exarane Safety-Lock
Enoxaparin	GRP-22378	Injection containing enoxaparin sodium 80 mg (8,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe	Injection	Clexane Safety-Lock Exarane Exarane Safety-Lock
Enoxaparin	GRP-22387	Injection containing enoxaparin sodium 20 mg (2,000 I.U. anti-Xa) in 0.2 mL pre-filled syringe	Injection	Clexane Safety-Lock Exarane Exarane Safety-Lock
Enoxaparin	GRP-28012	Injection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe	Injection	Clexane Forte Safety-Lock Exarane Forte Exarane Forte Safety-Lock
Enoxaparin	GRP-28013	Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre-filled syringe	Injection	Clexane Forte Safety-Lock Exarane Forte Exarane Forte Safety-Lock

[130] Schedule 5, entry for Entecavir *[GRP-21170]*

omit from the column headed "Brand": Entecavir Mylan

[131] Schedule 5, entry for Erlotinib *[GRP-24881]*

insert in the column headed "Brand" after entry for the Brand "Erlotinib APOTEX": ERLOTINIB ARX

[132] Schedule 5, omit entry for Estradiol *[GRP-28651]*

[133] Schedule 5, after entry for Estradiol *[GRP-29376]*

insert:

Estradiol	GRP-29483	Transdermal patches 1.56 mg, 24 (Sandoz) (S19A)	Transdermal	Estramon (Germany, Sandoz)
Estradiol	GRP-29483	Transdermal patches 1.56 mg, 24 (S19A)	Transdermal	Estramon 100 (Germany)
Estradiol with norethisterone	GRP-29485	Transdermal patches containing 620 micrograms estradiol (as hemihydrate) with 2.7 mg norethisterone acetate, 8	Transdermal	Estalis continuous 50/140
Estradiol with norethisterone	GRP-29485	Transdermal patches containing 620 micrograms estradiol (as hemihydrate) with 2.7 mg norethisterone acetate, 8 (S19A)	Transdermal	ESTALIS 140/50 (Canada)
Estradiol with norethisterone	GRP-29487	Transdermal patches containing 510 micrograms estradiol (as hemihydrate) with 4.8 mg norethisterone acetate, 8	Transdermal	Estalis continuous 50/250
Estradiol with norethisterone	GRP-29487	Transdermal patches containing 510 micrograms estradiol (as hemihydrate) with 4.8 mg norethisterone acetate, 8 (S19A)	Transdermal	ESTALIS 250/50 (Canada)

[134] Schedule 5, entry for Ethosuximide in the form Capsule 250 mg *[GRP-23067]*

omit from the column headed "Brand": Zarontin *substitute:* ZARONTIN

[135] Schedule 5, entry for Ezetimibe and rosuvastatin *[GRP-22369]*

insert in the column headed "Brand" after entry for the Brand "Ezalo Composite Pack 10mg+40mg": Ezetimibe - Rosuvastatin Sandoz 10 mg/40 mg

[136] Schedule 5, entry for Ezetimibe and rosuvastatin *[GRP-22388]*

insert in the column headed "Brand" after entry for the Brand "Ezalo Composite Pack 10mg+10mg": Ezetimibe - Rosuvastatin Sandoz 10 mg/10 mg

[137] Schedule 5, entry for Ezetimibe and rosuvastatin *[GRP-22395]*

insert in the column headed "Brand" after entry for the Brand "Ezalo Composite Pack 10mg+20mg": Ezetimibe - Rosuvastatin Sandoz 10 mg/20 mg

[138] Schedule 5, entry for Ezetimibe and rosuvastatin *[GRP-22399]*

insert in the column headed "Brand" after entry for the Brand "Ezalo Composite Pack 10mg+5mg": Ezetimibe - Rosuvastatin Sandoz 10 mg/5 mg

[139] Schedule 5, entries for Irbesartan

omit from the column headed "Brand" (all instances): Irbesartan GH

[140] Schedule 5, after entry for Leflunomide *[GRP-19866]*

insert:

Lenalidomide	GRP-29484	Capsule 20 mg	Oral	Lenalide Lenalidomide Sandoz

[141] Schedule 5, entry for Metformin *[GRP-19608]*

insert in the column headed "Brand" after entry for the Brand "METEX XR": Metformin Sandoz XR

[142] Schedule 5, entry for Metformin *[GRP-24200]*

substitute:

Metformin	GRP-24200	Tablet (extended release) containing metformin hydrochloride 500 mg	Oral	APO-Metformin XR 500 Diabex XR 500 Diaformin Alphapharm XR Metex XR Metformin Sandoz XR METFORMIN-WGR XR Pharmacor Metformin XR

[143] Schedule 5, entry for Modafinil

omit from the column headed "Brand": Modafinil Mylan

[144] Schedule 5, entry for Olanzapine in the form Tablet 10 mg (orally disintegrating) *[GRP-15723]*

omit from the column headed "Brand": Olanzapine ODT generichealth 10

[145] Schedule 5, entry for Pregabalin *[GRP-21640]*

omit from the column headed "Brand": Cipla Pregabalin

[146] Schedule 5, entry for Quetiapine [*GRP-19767]*

omit from the column headed "Brand": Quetiapine APOTEX

[147] Schedule 5, omit entry for Quinapril

[148] Schedule 5, entry for Ramipril in the form Tablet 5 mg *[GRP-15424]*

omit from the column headed "Brand": Tryzan Tabs 5

[149] Schedule 5, entry for Ramipril in the form Tablet 10 mg *[GRP-15431]*

omit from the column headed "Brand": Tryzan Tabs 10

[150] Schedule 5, entry for Ramipril in the form Tablet 1.25 mg *[GRP-15640]*

omit from the column headed "Brand": Tryzan Tabs 1.25

[151] Schedule 5, entry for Ramipril in the form Tablet 2.5 mg *[GRP-15769]*

omit from the column headed "Brand": Tryzan Tabs 2.5

[152] Schedule 5, entries for Timolol

omit:

Timolol	GRP-28880	Eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL (S19A)	Application to the eye	Timoptol XE 0.50% (South Africa)

[153] Schedule 5, after entry for Ursodeoxycholic acid

insert:

Ursodeoxycholic acid	GRP-29488	Capsule 500 mg	Oral	Ursodox GH
Ursodeoxycholic acid	GRP-29488	Tablet 500 mg	Oral	Ursofalk