



PB 17 of 2026

National Health (Listing of Pharmaceutical Benefits) Amendment (March Update) Instrument 2026

National Health Act 1953

I, REBECCA RICHARDSON, Assistant Secretary, PBS Listing, Pricing and Policy Branch, Technology Assessment and Access Division, Department of Health, Disability and Ageing, delegate of the Minister for Health and Ageing, make this Instrument under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

Dated 27 February 2026

REBECCA RICHARDSON
Assistant Secretary
PBS Listing, Pricing and Policy Branch
Technology Assessment and Access Division

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1. Name

- (1) This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (March Update) Instrument 2026*.
- (2) This Instrument may also be cited as PB 17 of 2026.

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 2026	1 March 2026

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Aflibercept in the form Solution for intravitreal injection 11.43 mg in 100 microlitres (114.3 mg per mL) [Maximum Quantity: 1; Number of Repeats: 5]

insert:

Aflibercept	Solution for intravitreal injection 11.43 mg in 100 microlitres (114.3 mg per mL) pre-filled syringe	Injection	Eylea	BN	MP	C13406 C15918 P13406 P15918	1	2	1
Aflibercept	Solution for intravitreal injection 11.43 mg in 100 microlitres (114.3 mg per mL) pre-filled syringe	Injection	Eylea	BN	MP	C13402 C17289 P13402 P17289	1	5	1

- [2] Schedule 1, Part 1, after entry for Aripiprazole in the form Powder for injection 300 mg (as monohydrate) with diluent

insert:

Aripiprazole	Powder for injection 300 mg (as monohydrate) with diluent in pre-filled dual-chamber syringe	Injection	Abilify Maintena	LU	MP NP	C4246	1	5	1
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- [3] Schedule 1, Part 1, after entry for Aripiprazole in the form Powder for injection 400 mg (as monohydrate) with diluent [Brand: ARIPENA]

insert:

Aripiprazole	Powder for injection 400 mg (as monohydrate) with diluent in pre-filled dual-chamber syringe	Injection	Abilify Maintena	LU	MP NP	C4246	1	5	1
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- [4] Schedule 1, Part 1, after entry for Atorvastatin in the form Tablet 10 mg (as calcium) [Brand: APO-Atorvastatin; Maximum Quantity: 60; Number of Repeats: 5]

insert:

Atorvastatin	Tablet 10 mg (as calcium)	Oral	ATOMED	DZ	MP		30	5	30
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Atorvastatin	Tablet 10 mg (as calcium)	Oral	ATOMED	DZ	MP NP	P14238	60	5	30
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[5] Schedule 1, Part 1, after entry for Atorvastatin in the form Tablet 20 mg (as calcium) [Brand: APO-Atorvastatin; Maximum Quantity: 60; Number of Repeats: 5]

insert:

Atorvastatin	Tablet 20 mg (as calcium)	Oral	ATOMED	DZ	MP NP		30	5	30
Atorvastatin	Tablet 20 mg (as calcium)	Oral	ATOMED	DZ	MP NP	P14238	60	5	30

[6] Schedule 1, Part 1, after entry for Atorvastatin in the form Tablet 40 mg (as calcium) [Brand: APO-Atorvastatin; Maximum Quantity: 60; Number of Repeats: 5]

insert:

Atorvastatin	Tablet 40 mg (as calcium)	Oral	ATOMED	DZ	MP NP		30	5	30
Atorvastatin	Tablet 40 mg (as calcium)	Oral	ATOMED	DZ	MP NP	P14238	60	5	30

[7] Schedule 1, Part 1, after entry for Atorvastatin in the form Tablet 80 mg (as calcium) [Brand: APO-Atorvastatin; Maximum Quantity: 60; Number of Repeats: 5]

insert:

Atorvastatin	Tablet 80 mg (as calcium)	Oral	ATOMED	DZ	MP NP		30	5	30
Atorvastatin	Tablet 80 mg (as calcium)	Oral	ATOMED	DZ	MP NP	P14238	60	5	30

[8] Schedule 1, Part 1, entry for Beclometasone with formoterol and glycopyrronium in the form Pressurised inhalation containing beclometasone dipropionate 100 micrograms with formoterol fumarate dihydrate 6 micrograms and glycopyrronium 10 micrograms (as bromide) per dose, 120 doses [Maximum Quantity: 2; Number of Repeats: 5]

(a) *insert in numerical order in the column headed "Circumstances":* C18121

(b) insert in numerical order in the column headed "Purposes": P18121

- [9] **Schedule 1, Part 1, entry for Beclometasone with formoterol and glycopyrronium in the form Pressurised inhalation containing beclometasone dipropionate 200 micrograms with formoterol fumarate dihydrate 6 micrograms and glycopyrronium 10 micrograms (as bromide) per dose, 120 doses**

insert in the column headed "Purposes": P12603

- [10] **Schedule 1, Part 1, after entry for Beclometasone with formoterol and glycopyrronium in the form Pressurised inhalation containing beclometasone dipropionate 200 micrograms with formoterol fumarate dihydrate 6 micrograms and glycopyrronium 10 micrograms (as bromide) per dose, 120 doses**

insert:

Beclometasone with formoterol and glycopyrronium	Pressurised inhalation containing beclometasone dipropionate 200 micrograms with formoterol fumarate dihydrate 6 micrograms and glycopyrronium 10 micrograms (as bromide) per dose, 120 doses	Inhalation by mouth	Trimbow	EU	MP NP	C18121	P18121	2	5	1
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- [11] **Schedule 1, Part 1, after entry for Betamethasone in the form Cream 500 micrograms (as dipropionate) per g, 15 g [Brand: Diprosone; Maximum Quantity: 10; Number of Repeats: 5]**

insert:

Betamethasone	Cream 500 micrograms (as dipropionate) per g, 15 g	Application	DIPROVANT	NB	MP NP	C4957	P4957	1	1	1
Betamethasone	Cream 500 micrograms (as dipropionate) per g, 15 g	Application	DIPROVANT	NB	MP NP	C6232	P6232	2	5	1
Betamethasone	Cream 500 micrograms (as dipropionate) per g, 15 g	Application	DIPROVANT	NB	MP NP	C6246	P6246	4	5	1
Betamethasone	Cream 500 micrograms (as dipropionate) per g, 15 g	Application	DIPROVANT	NB	MP NP	C6218	P6218	6	5	1
Betamethasone	Cream 500 micrograms (as dipropionate) per g, 15 g	Application	DIPROVANT	NB	MP NP	C6263	P6263	8	5	1

Betamethasone Cream 500 micrograms (as dipropionate) per g, 15 g	Application	DIPROVANT	NB	MP NP	C6231	P6231	10	5	1
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[12] Schedule 1, Part 1, after entry for Betamethasone in the form Ointment 500 micrograms (as dipropionate) per g, 15 g [Brand: Diprosone; Maximum Quantity: 10; Number of Repeats: 5]

insert:

Betamethasone Ointment 500 micrograms (as dipropionate) per g, 15 g	Application	DIPROVANT	NB	MP NP	C4957	P4957	1	1	1
Betamethasone Ointment 500 micrograms (as dipropionate) per g, 15 g	Application	DIPROVANT	NB	MP NP	C6232	P6232	2	5	1
Betamethasone Ointment 500 micrograms (as dipropionate) per g, 15 g	Application	DIPROVANT	NB	MP NP	C6246	P6246	4	5	1
Betamethasone Ointment 500 micrograms (as dipropionate) per g, 15 g	Application	DIPROVANT	NB	MP NP	C6218	P6218	6	5	1
Betamethasone Ointment 500 micrograms (as dipropionate) per g, 15 g	Application	DIPROVANT	NB	MP NP	C6263	P6263	8	5	1
Betamethasone Ointment 500 micrograms (as dipropionate) per g, 15 g	Application	DIPROVANT	NB	MP NP	C6231	P6231	10	5	1

[13] Schedule 1, Part 1, entry for Bimekizumab in the form Injection 160 mg in 1 mL single use pre-filled pen [Maximum Quantity: 2; Number of Repeats: 2]

- (a) omit from the column headed "Circumstances": C14375 C14376
- (b) insert in numerical order in the column headed "Circumstances": C18066 C18116
- (c) omit from the column headed "Purposes": P14375 P14376
- (d) insert in numerical order in the column headed "Purposes": P18066 P18116

[14] Schedule 1, Part 1, entry for Bimekizumab in the form Injection 160 mg in 1 mL single use pre-filled pen [Maximum Quantity: 2; Number of Repeats: 4]

- (a) omit from the column headed "Circumstances": C14374 C14396 C14425 C14437 C14448
- (b) omit from the column headed "Circumstances": C14460
- (c) insert in numerical order in the column headed "Circumstances": C18064 C18065 C18067 C18083 C18084 C18109

(d) omit from the column headed "Purposes": P14374 P14396 P14425 P14437 P14448

(e) omit from the column headed "Purposes": P14460

(f) insert in numerical order in the column headed "Purposes": P18064 P18065 P18067 P18083 P18084 P18109

[15] Schedule 1, Part 1, after entry for Bimekizumab in the form Injection 160 mg in 1 mL single use pre-filled pen [Maximum Quantity: 4; Number of Repeats: 3]

insert:

Bimekizumab	Injection 320 mg in 2 mL single use pre-filled pen	Injection	Bimzelx	UC	MP	C10807 C18066 C18116	P10807 P18066 P18116	1	2	1
Bimekizumab	Injection 320 mg in 2 mL single use pre-filled pen	Injection	Bimzelx	UC	MP	C14449 C18064 C18065 C18067 C18083 C18084 C18109	P14449 P18064 P18065 P18067 P18083 P18084 P18109	1	4	1

[16] Schedule 1, Part 1, entry for Blinatumomab

omit from the column headed "Circumstances": C16334

[17] Schedule 1, Part 1, after entry for Bortezomib in the form Solution for injection 2.5 mg in 1 mL [Brand: Bortezomib Ever Pharma]

insert:

Bortezomib	Solution for injection 2.5 mg in 1 mL	Injection	BORTRACZO	JM	MP	C11099 C13745		See Note 3	See Note 3	1	D(100)
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[18] Schedule 1, Part 1, after entry for Bortezomib in the form Solution for injection 3.5 mg in 1.4 mL [Brand: Bortezomib Ever Pharma]

insert:

Bortezomib	Solution for injection 3.5 mg in 1.4 mL	Injection	BORTRACZO	JM	MP	C11099 C13745		See Note 3	See Note 3	1	D(100)
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[19] Schedule 1, Part 1, after entry for Budesonide with formoterol in the form Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 60 doses [Authorised Prescriber: MP]

insert:

Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 60 doses	Inhalation	Bufomix Easyhaler OX		MP	C18055	P18055	4	5	1
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formoterol	breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 60 doses	by mouth	200/6		NP						
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 60 doses	Inhalation by mouth	Bufomix Easyhaler OX 200/6		MP	C18114	P18114	4	5		1

[20] Schedule 1, Part 1, entry for Dapagliflozin [Maximum Quantity: 56; Number of Repeats: 5]

- (a) insert in numerical order in the column headed "Circumstances": C18115
- (b) insert in numerical order in the column headed "Purposes": P18115
- (c) omit from the column headed "Pack Quantity": 56 substitute: 28

[21] Schedule 1, Part 1, after entry for Denosumab in the form Injection 60 mg in 1 mL pre-filled syringe [Brand: Prolia]

insert:

Denosumab	Injection 60 mg in 1 mL pre-filled syringe	Injection	Stoboclo		EW	MP NP	C6524 C6548	1	0		1
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[22] Schedule 1, Part 1, after entry for Denosumab in the form Injection 120 mg in 1.7 mL [Brand: GANVADO]

insert:

Denosumab	Injection 120 mg in 1.7 mL	Injection	Osenvelt		EW	MP NP	C16512 C16514 C16608	1	5		1
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[23] Schedule 1, Part 1, entries for Dicloxacillin

substitute:

Dicloxacillin	Capsule 250 mg (as sodium)	Oral	ARX-Dicloxacillin	XT		MP MW NP	C5415	24	0		24
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Dicloxacillin	Capsule 250 mg (as sodium)	Oral	ARX-Dicloxacillin	XT	PDP	C5268		24	0	24
Dicloxacillin	Capsule 250 mg (as sodium)	Oral	DICLOXACILLIN VIATRIS 250	MQ	MP MW NP	C5415		24	0	24
Dicloxacillin	Capsule 250 mg (as sodium)	Oral	DICLOXACILLIN VIATRIS 250	MQ	PDP	C5268		24	0	24
Dicloxacillin	Capsule 250 mg (as sodium)	Oral	Distaph 250	AF	MP MW NP	C5415		24	0	24
Dicloxacillin	Capsule 250 mg (as sodium)	Oral	Distaph 250	AF	PDP	C5268		24	0	24
Dicloxacillin	Capsule 500 mg (as sodium)	Oral	ARX-Dicloxacillin	XT	MP MW NP	C5415	P5415	24	0	24
Dicloxacillin	Capsule 500 mg (as sodium)	Oral	ARX-Dicloxacillin	XT	PDP	C5268	P5268	24	0	24
Dicloxacillin	Capsule 500 mg (as sodium)	Oral	ARX-Dicloxacillin	XT	MP	C6188	P6188	48	1	24
Dicloxacillin	Capsule 500 mg (as sodium)	Oral	DICLOXACILLIN VIATRIS 500	MQ	MP MW NP	C5415	P5415	24	0	24
Dicloxacillin	Capsule 500 mg (as sodium)	Oral	DICLOXACILLIN VIATRIS 500	MQ	PDP	C5268	P5268	24	0	24
Dicloxacillin	Capsule 500 mg (as sodium)	Oral	DICLOXACILLIN VIATRIS 500	MQ	MP	C6188	P6188	48	1	24
Dicloxacillin	Capsule 500 mg (as sodium)	Oral	Distaph 500	AF	MP MW NP	C5415	P5415	24	0	24
Dicloxacillin	Capsule 500 mg (as sodium)	Oral	Distaph 500	AF	PDP	C5268	P5268	24	0	24
Dicloxacillin	Capsule 500 mg (as sodium)	Oral	Distaph 500	AF	MP	C6188	P6188	48	1	24

sodium)

[24] Schedule 1, Part 1, entries for Drospirenone

omit:

Drospirenone	Pack containing 24 tablets 4 mg and 4 inert tablets, 3	Oral	Slinda	HB	MP MW NP			1	3		1
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[25] Schedule 1, Part 1, entry for Empagliflozin in the form Tablet 10 mg [Maximum Quantity: 60; Number of Repeats: 5]

(a) *insert in numerical order in the column headed "Circumstances":* C18113 C18115

(b) *insert in numerical order in the column headed "Purposes":* P18113 P18115

[26] 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: Clexane Safety-Lock; 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	Enoxaject	CR	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	Enoxaject	CR	MP NP	C4910	P4910	20	3		10

[27] 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: Clexane Safety-Lock; 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	Enoxaject	CR	MP MW NP	C16261	P16261	20	1		10
Enoxaparin	Injection containing enoxaparin sodium 40 mg (4,000 I.U. anti-Xa) in	Injection	Enoxaject	CR	MP NP	C4910	P4910	20	3		10

0.4 mL pre-filled syringe

[28] 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: Claxane Safety-Lock; Maximum Quantity: 20; Number of Repeats: 3]

insert:

Enoxaparin	Injection containing enoxaparin sodium 60 mg (6,000 I.U. anti-Xa) in 0.6 mL pre-filled syringe	Injection	Enojaxect	CR	MP MW NP	C16261	P16261	10	1	10
Enoxaparin	Injection containing enoxaparin sodium 60 mg (6,000 I.U. anti-Xa) in 0.6 mL pre-filled syringe	Injection	Enojaxect	CR	MP NP	C4910	P4910	20	3	10

[29] 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: Claxane Safety-Lock; 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	Enoxaject	CR	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	Enoxaject	CR	MP NP	C4910	P4910	20	3	10

[30] 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: Claxane Safety-Lock; 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	Enoxaject	CR	MP MW NP	C16261	P16261	10	1	10
Enoxaparin	Injection containing enoxaparin sodium 100 mg	Injection	Enoxaject	CR	MP	C4910	P4910	20	3	10

(10,000 I.U. anti-Xa) in 1 mL
pre-filled syringe

NP

[31] 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: Clexane Forte Safety-Lock]

insert:

Enoxaparin	Injection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe	Injection	Enoxaject	CR	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	Enoxaject	CR	MP NP	C4910	P4910	10	3	10

[32] 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: Clexane Forte Safety-Lock]

insert:

Enoxaparin	Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre-filled syringe	Injection	Enoxaject	CR	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	Enoxaject	CR	MP NP	C4910	P4910	10	3	10

[33] Schedule 1, Part 1, entry for Epcoritamab in the form Solution concentrate for subcutaneous injection 4 mg in 0.8 mL

omit from the column headed "Circumstances": C16405 *substitute:* C18106

[34] Schedule 1, Part 1, entries for Erlotinib in the form Tablet 100 mg (as hydrochloride)

omit:

Erlotinib	Tablet 100 mg (as hydrochloride)	Oral	Erlotinib APOTEX TX	MP	C4600 C7446 C16404			30	3	30
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[35] Schedule 1, Part 1, after entry for Etanercept in the form Injections 50 mg in 1 mL single use pre-filled syringes, 4 [Brand: Erelzi; Maximum Quantity: 1; Number of Repeats: 5]

insert:

Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Nepexto	GQ	MP	C12120 C17706 C17707 C17713 C17724 C17725	See Note 3	See Note 3	See Note 3	1	C(100)
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Nepexto	GQ	MP	C14508 C14509	P14508 P14509	1	1	1	
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Nepexto	GQ	MP	C9064 C9386 C12261 C14488 C14513 C14553 C14554 C14576 C14577 C14581 C14582 C14603 C14670 C14671 C14673 C14703 C16709 C16710 C16713 C16716 C16717 C16727 C16728 C16737 C16743 C16747 C16761 C16763 C16764 C16773 C16777 C16779 C16785 C16788 C17001 C17069 C17355	P9064 P9386 P12261 P14488 P14513 P14553 P14554 P14576 P14577 P14581 P14582 P14603 P14670 P14671 P14673 P14703 P16709 P16710 P16713 P16716 P16717 P16727 P16728 P16737 P16743 P16747 P16761 P16763 P16764 P16773 P16777 P16779 P16785 P16788 P17001 P17069 P17355	1	3	1	
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Nepexto	GQ	MP	C9081 C12123 C14499 C14507 C14629 C14683 C14701 C14715 C16718 C16720 C16725 C16750 C16754 C16765 C16766 C16772 C16775 C16778 C16787 C16789 C16792 C16795 C17326 C17374	P9081 P12123 P14499 P14507 P14629 P14683 P14701 P14715 P16718 P16720 P16725 P16750 P16754 P16765 P16766 P16772 P16775 P16778 P16787 P16789 P16792 P16795 P17326 P17374	1	5	1	

[36] Schedule 1, Part 1, after entry for Febuxostat in the form Tablet 80 mg [Maximum Quantity: 56; Number of Repeats: 5]

insert:

Felodipine	Tablet 2.5 mg (extended release)	Oral	Felodil XR 2.5	XT	MP NP		30	5	30
Felodipine	Tablet 2.5 mg (extended release)	Oral	Felodil XR 2.5	XT	MP NP	P14238	60	5	30

[37] Schedule 1, Part 1, after entry for Fenofibrate in the form Tablet 48 mg [Brand: APO-Fenofibrate; Maximum Quantity: 120; Number of Repeats: 5]

insert:

Fenofibrate	Tablet 48 mg	Oral	ARX-FENO-FIBRATE	TY	MP NP		60	5	60
Fenofibrate	Tablet 48 mg	Oral	ARX-FENO-FIBRATE	TY	MP NP	P14238	120	5	60

[38] Schedule 1, Part 1, after entry for Fenofibrate in the form Tablet 145 mg [Brand: APO-Fenofibrate; Maximum Quantity: 60; Number of Repeats: 5]

insert:

Fenofibrate	Tablet 145 mg	Oral	ARX-FENO-FIBRATE	TY	MP NP		30	5	30
Fenofibrate	Tablet 145 mg	Oral	ARX-FENO-FIBRATE	TY	MP NP	P14238	60	5	30

[39] Schedule 1, Part 1, after entry for Glipizide [Brand: Minidiab; Maximum Quantity: 200; Number of Repeats: 5]

insert:

Glofitamab	Solution concentrate for I.V. infusion 2.5 mg in 2.5 mL	Injection	Columvi	RO	MP	C18107		See Note 3	See Note 3	1	D(100)
Glofitamab	Solution concentrate for I.V. infusion 10 mg in 10 mL	Injection	Columvi	RO	MP	C18061 C18105 C18124		See Note 3	See Note 3	1	D(100)

[40] Schedule 1, Part 1, after entry for Inclisiran [Maximum Quantity: 1; Number of Repeats: 1]

insert:

IncobotulinumtoxinA Lyophilised powder for injection 100 units	Injection	Xeomin	EJ	MP	C18047 C18059 P18047 P18059	1	0		1	D(100)
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[41] Schedule 1, Part 1, entry for IncobotulinumtoxinA [Maximum Quantity: 4; Number of Repeats: 0]

insert in the column headed "Purposes": P5222 P5360 P9547

[42] Schedule 1, Part 1, entries for Indapamide in the form Tablet containing indapamide hemihydrate 1.5 mg (sustained release)

omit:

Indapamide	Tablet containing indapamide hemihydrate 1.5 mg (sustained release)	Oral	Tenaxil SR	RW	MP NP			90	1		90
Indapamide	Tablet containing indapamide hemihydrate 1.5 mg (sustained release)	Oral	Tenaxil SR	RW	MP NP	P14238		180	1		90

[43] Schedule 1, Part 1, entry for Ipilimumab in the form Injection concentrate for I.V. infusion 50 mg in 10 mL

omit from the column headed "Circumstances": C6562 C6585 C8555 C11391 C11478 C11930 C16936 *substitute:* C18069 C18071

[44] Schedule 1, Part 1, entry for Ipilimumab in the form Injection concentrate for I.V. infusion 200 mg in 40 mL

omit from the column headed "Circumstances": C6562 C6585 C16936 *substitute:* C18069 C18071

[45] Schedule 1, Part 1, entries for Ivabradine

substitute:

Ivabradine	Tablet 5 mg (as hydrochloride)	Oral	APO-Ivabradine	TX	MP NP	C4979	P4979	56	5		56
Ivabradine	Tablet 5 mg (as hydrochloride)	Oral	APO-Ivabradine	TX	MP NP	C18079	P18079	112	5		56
Ivabradine	Tablet 5 mg (as hydrochloride)	Oral	Coralan	SE	MP NP	C4979	P4979	56	5		56
Ivabradine	Tablet 5 mg (as hydrochloride)	Oral	Coralan	SE	MP NP	C18079	P18079	112	5		56

Ivabradine	Tablet 5 mg (as hydrochloride)	Oral	IVABRADINE-WGR	WG	MP NP	C4979	P4979	56	5	56
Ivabradine	Tablet 5 mg (as hydrochloride)	Oral	IVABRADINE-WGR	WG	MP NP	C18079	P18079	112	5	56
Ivabradine	Tablet 7.5 mg (as hydrochloride)	Oral	APO-Ivabradine	TX	MP NP	C4979	P4979	56	5	56
Ivabradine	Tablet 7.5 mg (as hydrochloride)	Oral	APO-Ivabradine	TX	MP NP	C18079	P18079	112	5	56
Ivabradine	Tablet 7.5 mg (as hydrochloride)	Oral	Coralan	SE	MP NP	C4979	P4979	56	5	56
Ivabradine	Tablet 7.5 mg (as hydrochloride)	Oral	Coralan	SE	MP NP	C18079	P18079	112	5	56

[46] Schedule 1, Part 1, entries for Levetiracetam in the form Tablet 250 mg

omit:

Levetiracetam	Tablet 250 mg	Oral	NOUMED LEVETIRACETAM	VO	MP NP	C17460	P17460	60	5	60
Levetiracetam	Tablet 250 mg	Oral	NOUMED LEVETIRACETAM	VO	MP NP	C17543	P17543	120	5	60

[47] Schedule 1, Part 1, entries for Levetiracetam in the form Tablet 500 mg

omit:

Levetiracetam	Tablet 500 mg	Oral	NOUMED LEVETIRACETAM	VO	MP NP	C17460	P17460	60	5	60
Levetiracetam	Tablet 500 mg	Oral	NOUMED LEVETIRACETAM	VO	MP NP	C17543	P17543	120	5	60

[48] Schedule 1, Part 1, entries for Levetiracetam in the form Tablet 1 g

omit:

Levetiracetam	Tablet 1 g	Oral	NOUMED LEVETIRACETAM	VO	MP NP	C17460	P17460	60	5	60
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Levetiracetam	Tablet 1 g	Oral	NOUMED LEVETIRACETAM	VO	MP NP	C17543	P17543	120	5	60
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[49] Schedule 1, Part 1, entries for Mometasone in the form Cream containing mometasone furoate 1 mg per g, 15 g

omit:

Mometasone	Cream containing mometasone furoate 1 mg per g, 15 g	Application	Momasone Alcohol Free	AS	MP NP	C4957	P4957	1	0	1
Mometasone	Cream containing mometasone furoate 1 mg per g, 15 g	Application	Momasone Alcohol Free	AS	MP NP	C6232	P6232	2	5	1
Mometasone	Cream containing mometasone furoate 1 mg per g, 15 g	Application	Momasone Alcohol Free	AS	MP NP	C6246	P6246	4	5	1
Mometasone	Cream containing mometasone furoate 1 mg per g, 15 g	Application	Momasone Alcohol Free	AS	MP NP	C6218	P6218	6	5	1
Mometasone	Cream containing mometasone furoate 1 mg per g, 15 g	Application	Momasone Alcohol Free	AS	MP NP	C6263	P6263	8	5	1
Mometasone	Cream containing mometasone furoate 1 mg per g, 15 g	Application	Momasone Alcohol Free	AS	MP NP	C6231	P6231	10	5	1

[50] Schedule 1, Part 1, entries for Mometasone in the form Ointment containing mometasone furoate 1 mg per g, 15 g

omit:

Mometasone	Ointment containing mometasone furoate 1 mg per g, 15 g	Application	Momasone	AS	MP NP	C4957	P4957	1	0	1
Mometasone	Ointment containing mometasone furoate 1 mg per g, 15 g	Application	Momasone	AS	MP NP	C6232	P6232	2	5	1
Mometasone	Ointment containing mometasone furoate 1 mg per g, 15 g	Application	Momasone	AS	MP NP	C6246	P6246	4	5	1

	per g, 15 g								
Mometasone	Ointment containing mometasone furoate 1 mg per g, 15 g	Application Momasone	AS	MP NP	C6218	P6218	6	5	1
Mometasone	Ointment containing mometasone furoate 1 mg per g, 15 g	Application Momasone	AS	MP NP	C6263	P6263	8	5	1
Mometasone	Ointment containing mometasone furoate 1 mg per g, 15 g	Application Momasone	AS	MP NP	C6231	P6231	10	5	1

[51] Schedule 1, Part 1, entry for Nivolumab in the form Injection concentrate for I.V. infusion 40 mg in 4 mL

- (a) omit from the column headed "Circumstances": C9216 C9252 C9298 C9299 C9312 C9321 C11468 C11477 C11985 C13445 C13839
- (b) omit from the column headed "Circumstances": C14001 C14830
- (c) omit from the column headed "Circumstances": C16657 C16755 C16790
- (d) omit from the column headed "Circumstances": C16961
- (e) omit from the column headed "Circumstances": C17360
- (f) insert in numerical order in the column headed "Circumstances": C18070
- (g) omit from the column headed "Variations": V16755

[52] Schedule 1, Part 1, entry for Nivolumab in the form Injection concentrate for I.V. infusion 100 mg in 10 mL

- (a) omit from the column headed "Circumstances": C9216 C9252 C9298 C9299 C9312 C9321 C11468 C11477 C11985 C13445 C13839
- (b) omit from the column headed "Circumstances": C14001 C14830
- (c) omit from the column headed "Circumstances": C16657 C16755 C16790
- (d) omit from the column headed "Circumstances": C16961
- (e) omit from the column headed "Circumstances": C17360
- (f) insert in numerical order in the column headed "Circumstances": C18070
- (g) omit from the column headed "Variations": V16755

[53] Schedule 1, Part 1, entries for Obinutuzumab

substitute:

Obinutuzumab	Solution for I.V. infusion 1000 mg in 40 mL	Injection	Gazyva	RO	MP	C11015 C11755 C11785 C11787 C11815 C14326 C14764 C18082		See Note 3	See Note 3	1	D(100)
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[54] Schedule 1, Part 1, entry for Opicapone

substitute:

Opicapone	Capsule 50 mg	Oral	Ongentys	XY	MP NP	C16651	P16651	30	5	30
Opicapone	Capsule 50 mg	Oral	Ongentys	XY	MP NP	C18125	P18125	60	5	30

[55] Schedule 1, Part 1, entry for Osilodrostat in the form Tablet 1 mg (as phosphate) [Maximum Quantity: 60; Number of Repeats: 6]

(a) omit from the column headed "Circumstances": C16349

(b) omit from the column headed "Purposes": P16349

[56] Schedule 1, Part 1, entry for Osilodrostat in the form Tablet 5 mg (as phosphate) [Maximum Quantity: 60; Number of Repeats: 6]

(a) omit from the column headed "Circumstances": C16349

(b) omit from the column headed "Purposes": P16349

[57] Schedule 1, Part 1, after entry for Pioglitazone in the form Tablet 15 mg (as hydrochloride) [Brand: Vexazone; Maximum Quantity: 56; Number of Repeats: 5]

insert:

Pioglitazone	Tablet 15 mg (as hydrochloride), pack of 30	Oral	Actos	GQ	MP NP	C15321	P15321	1	5	1
Pioglitazone	Tablet 15 mg (as hydrochloride), pack of 30	Oral	Actos	GQ	MP NP	C15290	P15290	2	5	1

[58] Schedule 1, Part 1, after entry for Pioglitazone in the form Tablet 30 mg (as hydrochloride) [Brand: Vexazone; Maximum Quantity: 56; Number of Repeats: 5]

insert:

Pioglitazone	Tablet 30 mg (as	Oral	Actos	GQ	MP	C15321	P15321	1	5	1
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insert:

Tenofovir with emtricitabine and efavirenz	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and efavirenz 600 mg (s19A)	Oral	Efavirenz, Emtricitabine QY and Tenofovir Disoproxil Fumarate Tablet 600 mg/200 mg/300 mg (Camber, USA)	MP NP	C4470 C4522	60	5	30	D(100)
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[64] Schedule 1, Part 2, omit entry for Bethanechol

[65] Schedule 1, Part 2, after entry for Brimonidine

insert:

Drospirenone	Pack containing 24 tablets 4 mg and 4 inert tablets, 3	Oral	Slinda	HB	1
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[66] Schedule 1, Part 2, omit entry for Promethazine

[67] Schedule 1, Part 2, omit entry for Silver sulfadiazine

[68] Schedule 4, Part 1, omit entry for Circumstances Code "C6562"

[69] Schedule 4, Part 1, omit entry for Circumstances Code "C6585"

[70] Schedule 4, Part 1, omit entry for Circumstances Code "C8555"

[71] Schedule 4, Part 1, omit entry for Circumstances Code "C9216"

[72] Schedule 4, Part 1, omit entry for Circumstances Code "C9252"

[73] Schedule 4, Part 1, omit entry for Circumstances Code "C9298"

[74] Schedule 4, Part 1, omit entry for Circumstances Code "C9299"

[75] Schedule 4, Part 1, omit entry for Circumstances Code "C9312"

[76] Schedule 4, Part 1, omit entry for Circumstances Code "C9321"

[77] Schedule 4, Part 1, omit entry for Circumstances Code "C11391"

[78] Schedule 4, Part 1, omit entry for Circumstances Code "C11468"

[79] Schedule 4, Part 1, omit entry for Circumstances Code "C11477"

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- [80] Schedule 4, Part 1, omit entry for Circumstances Code “C11478”
- [81] Schedule 4, Part 1, omit entry for Circumstances Code “C11930”
- [82] Schedule 4, Part 1, omit entry for Circumstances Code “C11985”
- [83] Schedule 4, Part 1, omit entry for Circumstances Code “C13445”
- [84] Schedule 4, Part 1, omit entry for Circumstances Code “C13839”
- [85] Schedule 4, Part 1, omit entry for Circumstances Code “C14001”
- [86] Schedule 4, Part 1, omit entry for Circumstances Code “C14374”
- [87] Schedule 4, Part 1, omit entry for Circumstances Code “C14375”
- [88] Schedule 4, Part 1, omit entry for Circumstances Code “C14376”
- [89] Schedule 4, Part 1, omit entry for Circumstances Code “C14396”
- [90] Schedule 4, Part 1, omit entry for Circumstances Code “C14425”
- [91] Schedule 4, Part 1, omit entry for Circumstances Code “C14437”
- [92] Schedule 4, Part 1, omit entry for Circumstances Code “C14448”
- [93] Schedule 4, Part 1, omit entry for Circumstances Code “C14460”
- [94] Schedule 4, Part 1, omit entry for Circumstances Code “C14830”
- [95] Schedule 4, Part 1, entry for Circumstances Code “C15556”
insert in alphabetical order in the column headed “Listed Drug”: Propylene glycol
- [96] Schedule 4, Part 1, omit entry for Circumstances Code “C16334”
- [97] Schedule 4, Part 1, omit entry for Circumstances Code “C16348”
- [98] Schedule 4, Part 1, omit entry for Circumstances Code “C16349”
- [99] Schedule 4, Part 1, omit entry for Circumstances Code “C16405”
- [100] Schedule 4, Part 1, omit entry for Circumstances Code “C16657”

- [101] Schedule 4, Part 1, omit entry for Circumstances Code “C16755”
- [102] Schedule 4, Part 1, omit entry for Circumstances Code “C16790”
- [103] Schedule 4, Part 1, omit entry for Circumstances Code “C16936”
- [104] Schedule 4, Part 1, omit entry for Circumstances Code “C16961”
- [105] Schedule 4, Part 1, omit entry for Circumstances Code “C17360”
- [106] Schedule 4, Part 1, after entry for Circumstances Code “C18039”

insert:

C18047	P18047	CN18047	IncobotulinumtoxinA	<p>Chronic sialorrhoea</p> <p>Patient must be initiating treatment with a Drooling Severity and Frequency Scale (DSFS) score of at least 6. or</p> <p>Patient must be continuing treatment with improvement in the DSFS score of at least 1 point from baseline as assessed by the treating clinician. AND</p> <p>Patient must have cerebral palsy. or</p> <p>Patient must have traumatic brain injury. or</p> <p>Patient must have developmental disorder.</p> <p>Patient must be aged from 2 to 17 years inclusive.</p> <p>Must be treated by a neurologist. or</p> <p>Must be treated by a rehabilitation specialist. or</p> <p>Must be treated by a paediatrician. or</p> <p>Must be treated by an otolaryngologist surgeon. or</p> <p>Must be treated by a plastic surgeon.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 18047
C18055	P18055	CN18055	Budesonide with formoterol	<p>Asthma</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. AND</p> <p>Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids. or</p> <p>Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy. or</p> <p>Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and</p>	Compliance with Authority Required procedures - Streamlined Authority Code 18055

				require single maintenance and reliever therapy.	
C18059	P18059	CN18059	IncobotulinumtoxinA	<p>Chronic sialorrhea</p> <p>Patient must be initiating treatment with a Drooling Severity and Frequency Scale (DSFS) score of at least 6. or</p> <p>Patient must be continuing treatment with improvement in the DSFS score of at least 1 point from baseline as assessed by the treating clinician. AND</p> <p>Patient must have Parkinson's disease. or</p> <p>Patient must have atypical Parkinson's. or</p> <p>Patient must have traumatic brain injury. or</p> <p>Patient must have chronic sialorrhea following an acute event.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a neurologist. or</p> <p>Must be treated by a rehabilitation specialist. or</p> <p>Must be treated by a geriatrician. or</p> <p>Must be treated by an otolaryngologist surgeon. or</p> <p>Must be treated by a plastic surgeon.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 18059
C18061	P18061	CN18061	Glofitamab	<p>Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)</p> <p>Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this PBS condition prior to 1 March 2026. AND</p> <p>Patient must have been unable to receive treatment with CAR-T cell therapy prior to commencing treatment with this drug for this condition. AND</p> <p>Patient must have been unsuitable for stem cell transplant prior to commencing treatment with this drug for this condition. AND</p> <p>Patient must have had a WHO performance status of 2 or less prior to commencing treatment with this drug for this condition. AND</p> <p>Patient must not have developed disease progression while being treated with this drug for this condition. AND</p> <p>The treatment must be given in combination with gemcitabine and oxaliplatin for the first 8 cycles unless the patient has a contraindication/toxicity necessitating discontinuation of one or both chemotherapy components. AND</p> <p>The treatment must not exceed a total of 12 cycles of this drug for this indication, regardless of whether treatment was non-PBS or PBS-subsidised.</p>	Compliance with Authority Required procedures
C18064	P18064	CN18064	Bimekizumab	Severe chronic plaque psoriasis	Compliance with Written

				<p>Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition. AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition. AND</p> <p>The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15. AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate). AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a dermatologist.</p> <p>The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) details of the proposed prescription(s); and</p> <p>(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) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.</p> <p>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.</p> <p>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.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	Authority Required procedures
C18065	P18065	CN18065	Bimekizumab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine</p>	Compliance with Written Authority Required procedures

for this condition in this treatment cycle. AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle. AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle. AND

The treatment must be as systemic monotherapy (other than methotrexate). AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Patient must be at least 18 years of age.

Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

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.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); 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) which includes the following:

				<p>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of prior biological treatment, including dosage, date and duration of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>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.</p>	
C18066	P18066	CN18066	Bimekizumab	<p>Severe chronic plaque psoriasis</p> <p>Continuing treatment, Face, hand, foot</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition. AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug. AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate). AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a dermatologist.</p> <p>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:</p> <p>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or</p> <p>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) details of the proposed prescription(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.</p> <p>The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>Approval will be based on the PASI assessment of response to the most recent</p>	Compliance with Written Authority Required procedures

				<p>course of treatment with this drug.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>An application for the continuing treatment 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 treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>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.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>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.</p>	
C18067	P18067	CN18067	Bimekizumab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition. AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition. AND</p> <p>The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate). AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a dermatologist.</p> <p>The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>The PASI assessment for continuing treatment must be performed on the same</p>	Compliance with Written Authority Required procedures

				<p>affected area as assessed at baseline.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) details of the proposed prescription(s); and</p> <p>(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) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.</p> <p>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.</p> <p>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.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C18069	P18069	CN18069	Ipilimumab	<p>Stage III melanoma</p> <p>Patient must not have received prior PBS-subsidised treatment for this condition. AND</p> <p>The treatment must be in addition to complete surgical resection. AND</p> <p>Patient must have a WHO performance status of 1 or less. AND</p> <p>The treatment must be in combination with PBS-subsidised treatment with nivolumab.</p> <p>Prescribed amounts must be consistent with the treatment protocol used for an individual patient.</p> <p>When ipilimumab is initially prescribed as a 3-weekly dosing regimen, patients must only receive a maximum of 80 mg every 3 weeks for 2 cycles (i.e., 1 repeat), in combination with nivolumab.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 18069
C18070	P18070	CN18070	Nivolumab	<p>Immunotherapy sensitive advanced or metastatic cancer</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for the condition which treatment was commenced for.</p> <p>Patients must only receive a maximum of 240 mg every two weeks, 360 mg every three weeks, or 480 mg every four weeks under a weight based or flat dosing</p>	Compliance with Authority Required procedures - Streamlined Authority Code 18070

				regimen.	
C18071	P18071	CN18071	Ipilimumab	<p>Immunotherapy sensitive advanced or metastatic cancer</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for the condition which treatment was commenced for.</p> <p>The stated maximum amount in this listing is 360 mg however alternative dosing schedules may be prescribed in a quantity up to this amount, but need not be this amount for every cancer type.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 18071
C18079	P18079	CN18079	Ivabradine	<p>Chronic heart failure</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. AND</p> <p>Patient must be symptomatic with NYHA classes II or III. AND</p> <p>Patient must be in sinus rhythm. AND</p> <p>Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%. AND</p> <p>Patient must have a resting heart rate at or above 77 bpm at the time ivabradine treatment is initiated. AND</p> <p>Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated.</p> <p>Resting heart rate should be measured by ECG or echocardiography, after 5 minutes rest.</p> <p>The ECG or echocardiography, result must be documented in the patient's medical records when treatment is initiated.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 18079
C18082	P18082	CN18082	Obinutuzumab	<p>Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)</p> <p>Pre-treatment prior to initiation of glofitamab</p> <p>Patient must be eligible to receive treatment under the PBS listing criteria for glofitamab.</p> <p>Patient is intended to receive a single dose of Obinutuzumab 1000 mg 7 days prior to initiating glofitamab treatment (Cycle 1, Day 1).</p>	Compliance with Authority Required procedures - Streamlined Authority Code 18082
C18083	P18083	CN18083	Bimekizumab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Whole body (new patient)</p> <p>Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis. AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine</p>	Compliance with Written Authority Required procedures

for this condition. AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks. AND

The treatment must be as systemic monotherapy (other than methotrexate). AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Patient must be at least 18 years of age.

Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription(s); 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) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

C18084	P18084	CN18084	Bimekizumab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle. AND</p> <p>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</p> <p>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</p> <p>The treatment must be as systemic monotherapy (other than methotrexate). AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a dermatologist.</p> <p>An adequate response to treatment is defined as:</p> <p>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.</p> <p>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</p>	Compliance with Written Authority Required procedures
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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.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription(s); 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) which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

C18105	P18105	CN18105	Glofitamab	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) Continuing treatment (Cycles 2-12) Patient must have previously received PBS-subsidised treatment with this drug for this condition. AND The treatment must be given in combination with gemcitabine and oxaliplatin for the first 8 cycles unless the patient has a contraindication/toxicity necessitating discontinuation of one or both chemotherapy components. AND Patient must not have developed disease progression while being treated with this drug for this condition. AND The treatment must not exceed a total of 12 cycles of this drug for this indication, regardless of whether treatment was non-PBS or PBS-subsidised.	Compliance with Authority Required procedures
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C18106	P18106	CN18106	Epcoritamab	<p>Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) Induction treatment</p> <p>The condition must have relapsed, or be refractory to, at least two prior systemic therapies. AND</p> <p>Patient must have a WHO performance status of no higher than 2. AND</p> <p>Patient must have previously received treatment with chimeric antigen receptor-T (CAR-T) cell therapy for this condition. or</p> <p>Patient must be currently unable to receive treatment with CAR-T cell therapy for this condition. AND</p> <p>Patient must not be eligible for stem cell transplantation. AND</p> <p>Patient must not have received prior treatment with a PBS-subsidised CD20xCD3 bispecific monoclonal antibody. AND</p> <p>The treatment must be discontinued in patients who experience disease progression whilst on treatment.</p> <p>Prior systemic therapy may include autologous stem cell transplant.</p> <p>Definition of patients unable to receive treatment with CAR-T cell therapy for this condition include geographical, psychosocial, clinical ineligibility or urgency.</p>	Compliance with Authority Required procedures
C18107	P18107	CN18107	Glofitamab	<p>Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) Initial treatment (Cycle 1, Day 8)</p> <p>Patient must be currently unable to receive treatment with CAR-T cell therapy for this condition. AND</p> <p>Patient must be unsuitable for stem cell transplant. AND</p> <p>Patient must have a WHO performance status of 2 or less. AND</p> <p>Patient must have received or intend to receive a single pre-treatment dose of obinutuzumab for this indication. AND</p> <p>The treatment must be given in combination with gemcitabine and oxaliplatin for the first 8 cycles unless the patient has a contraindication/toxicity necessitating discontinuation of one or both chemotherapy components.</p> <p>Definition of patients unable to receive treatment with CAR-T cell therapy for this condition include geographical, psychosocial, clinical ineligibility or urgency.</p> <p>Glofitamab should be administered as an intravenous infusion according to the dose step-up schedule in Cycle 1 (2.5 mg on Day 8 and 10 mg on Day 15) leading to the recommended dosage of 30 mg on Day 1 of Cycles 2-12. Refer to the TGA approved Product Information.</p> <p>This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p>	Compliance with Authority Required procedures

C18109	P18109	CN18109	Bimekizumab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Face, hand, foot (new patient)</p> <p>Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis. AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition. AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks. AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate). AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:</p> <p>(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or</p> <p>(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot,</p>	Compliance with Written Authority Required procedures
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as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); 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) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

C18113	P18113	CN18113	Empagliflozin	Chronic heart failure The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. AND Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug. AND Patient must have a documented left ventricular ejection fraction (LVEF) of greater	Compliance with Authority Required procedures - Streamlined Authority Code 18113
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				<p>than 40%. AND</p> <p>Patient must have documented evidence of structural changes in the heart on echocardiography that would be expected to cause diastolic dysfunction (e.g. left ventricular hypertrophy). AND</p> <p>Patient must have documented evidence of at least one of the following: (i) diastolic dysfunction with high filling pressure on echocardiography, stress echocardiography or cardiac catheterisation; (ii) hospitalisation for heart failure in the 12 months prior to initiating treatment with this drug; (iii) requirement for intravenous diuretic therapy in the 12 months prior to initiating treatment with this drug; (iv) elevated N-terminal pro brain natriuretic peptide (NT-proBNP) levels in the absence of another cause. AND</p> <p>Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.</p>	
C18114	P18114	CN18114	Budesonide with formoterol	<p>Asthma</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. AND</p> <p>Patient must have failed PBS-subsidised fluticasone propionate and salmeterol as a fixed dose combination for this condition.</p> <p>Must be treated by a respiratory physician. or</p> <p>Must be treated by a paediatrician.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 18114
C18115	P18115	CN18115	Dapagliflozin Empagliflozin	<p>Chronic kidney disease</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. AND</p> <p>Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug. AND</p> <p>Patient must have an estimated glomerular filtration rate of between 20 to 90 mL/min/1.73 m² inclusive prior to initiating treatment with this drug. AND</p> <p>Patient must have a urinary albumin to creatinine ratio of at least 200 mg/g (22.6 mg/mmol) if the patient has an estimated glomerular filtration rate of between 45 to 90 mL/min/1.73 m² inclusive prior to initiating treatment with this drug. AND</p> <p>Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant. AND</p> <p>Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor. AND</p> <p>Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 18115

				<p>Patients with polycystic kidney disease, lupus nephritis or ANCA-associated vasculitis; patients requiring or with a recent history of cytotoxic or immunosuppressive therapy for kidney disease; and patients with an organ transplant are not eligible for treatment with this drug.</p>	
C18116	P18116	CN18116	Bimekizumab	<p>Severe chronic plaque psoriasis Continuing treatment, Whole body Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition. AND Patient must have demonstrated an adequate response to treatment with this drug. AND The treatment must be as systemic monotherapy (other than methotrexate). AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 4 weeks old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. An application for the continuing treatment 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 treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised 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 under this</p>	Compliance with Written Authority Required procedures

				<p>restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>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.</p>	
C18121	P18121	CN18121	Beclometasone with formoterol and glycopyrronium	<p>Severe asthma</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. AND</p> <p>Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.</p> <p>Patient must be at least 18 years of age.</p> <p>Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 18121
C18124	P18124	CN18124	Glofitamab	<p>Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)</p> <p>Initial treatment (Cycle 1, Day 15)</p> <p>Patient must be currently unable to receive treatment with CAR-T cell therapy for this condition. AND</p> <p>Patient must be unsuitable for stem cell transplant. AND</p> <p>Patient must have a WHO performance status of 2 or less. AND</p> <p>Patient must have received or intend to receive a Cycle 1, Day 8 dose of glofitamab for this indication. AND</p> <p>The treatment must be given in combination with gemcitabine and oxaliplatin for the first 8 cycles unless the patient has a contraindication/toxicity necessitating discontinuation of one or both chemotherapy components.</p> <p>Glofitamab should be administered as an intravenous infusion according to the dose step-up schedule in Cycle 1 (2.5 mg on Day 8 and 10 mg on Day 15) leading to the recommended dosage of 30 mg on Day 1 of Cycles 2-12. Refer to the TGA approved Product Information.</p>	Compliance with Authority Required procedures
C18125	P18125	CN18125	Opicapone	<p>Parkinson disease</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. AND</p>	

The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination. AND
 Patient must be experiencing fluctuations in motor function due to end-of-dose effect.
 Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

[107] Schedule 4, Part 2, omit entry for Variation Code “V16755”

[108] Schedule 5, after entry for Aflibercept in the form Solution for intravitreal injection 6.6 mg in 165 microlitres (40 mg per mL) pre-filled syringe

insert:

Aflibercept	GRP-30410	Solution for intravitreal injection 11.43 mg in 100 microlitres (114.3 mg per mL)	Injection	Eylea
Aflibercept	GRP-30410	Solution for intravitreal injection 11.43 mg in 100 microlitres (114.3 mg per mL) pre-filled syringe	Injection	Eylea

[109] Schedule 5, entry for Atorvastatin [GRP-1196]

insert in the column headed “Brand” after entry for the brand “APO-Atorvastatin”: ATOMED

[110] Schedule 5, entry for Atorvastatin [GRP-1197]

insert in the column headed “Brand” after entry for the brand “APO-Atorvastatin”: ATOMED

[111] Schedule 5, entry for Atorvastatin [GRP-1198]

insert in the column headed “Brand” after entry for the brand “APO-Atorvastatin”: ATOMED

[112] Schedule 5, entry for Atorvastatin [GRP-1199]

insert in the column headed “Brand” after entry for the brand “APO-Atorvastatin”: ATOMED

[113] Schedule 5, entry for Betamethasone [GRP-965]

insert in the column headed “Brand” after entry for the brand “Diprosone”: DIPROVANT

[114] Schedule 5, entry for Betamethasone [GRP-966]

insert in the column headed “Brand” after entry for the brand “Diprosone”: DIPROVANT

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- [115] **Schedule 5, entry for Denosumab [GRP-29689]**
insert in the column headed "Brand" after entry for the brand "Prolia": Stoboclo
- [116] **Schedule 5, entry for Denosumab [GRP-29690]**
insert in the column headed "Brand" after entry for the brand "GANVADO": Osenvelt
- [117] **Schedule 5, entry for Dicloxacillin [GRP-1162]**
insert as the first entry in the column headed "Brand": ARX-Dicloxacillin
- [118] **Schedule 5, entry for Dicloxacillin [GRP-22250]**
insert as the first entry in the column headed "Brand": ARX-Dicloxacillin
- [119] **Schedule 5, entry for Enoxaparin [GRP-21948]**
insert in the column headed "Brand" after entry for the brand "Clexane Safety-Lock": Enoxaject
- [120] **Schedule 5, entry for Enoxaparin [GRP-21950]**
insert in the column headed "Brand" after entry for the brand "Clexane Safety-Lock": Enoxaject
- [121] **Schedule 5, entry for Enoxaparin [GRP-21958]**
insert in the column headed "Brand" after entry for the brand "Clexane Safety-Lock": Enoxaject
- [122] **Schedule 5, entry for Enoxaparin [GRP-21960]**
insert in the column headed "Brand" after entry for the brand "Clexane Safety-Lock": Enoxaject
- [123] **Schedule 5, entry for Enoxaparin [GRP-21962]**
insert in the column headed "Brand" after entry for the brand "Clexane Safety-Lock": Enoxaject
- [124] **Schedule 5, entry for Enoxaparin [GRP-27957]**
insert in the column headed "Brand" after entry for the brand "Clexane Forte Safety-Lock": Enoxaject
- [125] **Schedule 5, entry for Enoxaparin [GRP-27959]**
insert in the column headed "Brand" after entry for the brand "Clexane Forte Safety-Lock": Enoxaject
- [126] **Schedule 5, entry for Erlotinib [GRP-24728]**
omit from the column headed "Brand": Erlotinib APOTEX
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[127] Schedule 5, entry for Etanercept in the form Injections 50 mg in 1 mL single use pre-filled syringes, 4

insert in the column headed "Brand" after entry for the brand "Erelzi": Nepexto

[128] Schedule 5, entry for Felodipine [GRP-768]

insert as the first entry in the column headed "Brand": Felodil XR 2.5

[129] Schedule 5, entry for Fenofibrate [GRP-20649]

insert in the column headed "Brand" after entry for the brand "APO-Fenofibrate": ARX-FENOFIBRATE

[130] Schedule 5, entry for Fenofibrate [GRP-20651]

insert in the column headed "Brand" after entry for the brand "APO-Fenofibrate": ARX-FENOFIBRATE

[131] Schedule 5, entry for Indapamide [GRP-15111]

omit from the column headed "Brand": Tenaxil SR

[132] Schedule 5, entry for Levetiracetam [GRP-686]

omit from the column headed "Brand": NOUMED LEVETIRACETAM

[133] Schedule 5, entry for Levetiracetam [GRP-687]

omit from the column headed "Brand": NOUMED LEVETIRACETAM

[134] Schedule 5, entry for Levetiracetam [GRP-688]

omit from the column headed "Brand": NOUMED LEVETIRACETAM

[135] Schedule 5, entry for Mometasone [GRP-1102]

omit from the column headed "Brand": Momasone Alcohol Free

[136] Schedule 5, entry for Mometasone [GRP-1104]

omit from the column headed "Brand": Momasone

[137] Schedule 5, after entry for Pravastatin [GRP-1040]

insert:

Praziquantel	GRP-30503	Tablet 600 mg (Korea) (s19A)	Oral	Distocide (Korea)
Praziquantel	GRP-30503	Tablet 600 mg (s19A)	Oral	Praziquantel Tablets, USP 600 mg

				(Endo, USA)
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[138] Schedule 5, after entry for Tenofovir with emtricitabine in the form Tablet containing tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg

insert:

Tenofovir with emtricitabine and efavirenz	GRP-23126	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and efavirenz 600 mg (s19A)	Oral	Efavirenz, Emtricitabine and Tenofovir Disoproxil Fumarate Tablet 600 mg/200 mg/300 mg (Camber, USA)
Tenofovir with emtricitabine and efavirenz	GRP-23126	Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg and efavirenz 600 mg	Oral	Tenofovir Disoproxil Emtricitabine Efavirenz Viartis 300/200/600