PB 39 of 2024

National Health (Listing of Pharmaceutical Benefits) Amendment (May Update) Instrument 2024

National Health Act 1953

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

Dated 29 April 2024

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

Contents

1 Name

(1) This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (May Update) Instrument 2024*.

(2) This Instrument may also be cited as PB 39 of 2024.

2 Commencement

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

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

Note: This table relates only to the provisions of this instrument as originally made.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

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

3 Authority

This instrument is made under 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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, entry for Abemaciclib in each of the forms: Tablet 50 mg; Tablet 100 mg; and Tablet 150 mg

omit from the column headed "Circumstances": **C13035 C13036** *substitute:* **C15186 C15218 C15219**

[2] Schedule 1, Part 1, entry for Alirocumab in each of the forms: Injection 75 mg in 1 mL single use pre-filled pen; and Injection 150 mg in 1 mL single use pre-filled pen

(a) *omit from the column headed "Circumstances":* **C15077 C15080**

(b) *insert in numerical order in the column headed "Circumstances":* **C15177 C15201**

[3] Schedule 1, Part 1, entry for Amino acid formula with vitamins and minerals without lysine and low in tryptophan

omit:

Amino acid formula with vitamins and minerals without lysine and low in tryptophan	Sachets containing oral powder 25 g, 30 (GA express 15)	Oral	GA express 15	VF	MP NP	C5323 C11482	4	5	1

[4] Schedule 1, Part 1, after entry for Amino acid formula with vitamins and minerals without methionine in the form Sachets containing oral powder 36 g, 30 (HCU Anamix Junior)

insert:

Amino acid formula with vitamins and minerals without methionine and supplemented with arachidonic acid and docosahexaen	Sachets containing oral powder 12.5 g, 30 (HCU explore5)	Oral	HCU explore5	VF	MP NP	C5534	8	5	1

oic acid										

[5] Schedule 1, Part 1, after entry for Amino acid formula with vitamins and minerals without phenylalanine and tyrosine in the form Sachets containing oral powder 36 g, 30 (TYR Anamix Junior)

insert:

Amino acid formula with vitamins and minerals, without phenylalanine, tyrosine and supplemented with arachidonic acid and docosahexaenoic acid	Sachets containing oral powder 12.5 g, 30 (TYR explore5)	Oral	TYR explore5	VF	MP NP	C5533	8	5	1

[6] Schedule 1, Part 1, after entry for Amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexanoic acid in the form Oral liquid 125 mL, 36 (MSUD Anamix Junior LQ)

insert:

Amino acid formula with vitamins and minerals without valine, leucine, isoleucine and supplemented with arachidonic acid and docosahexaenoic acid	Sachets containing oral powder 12.5 g, 30 (MSUD Explore5)	Oral	MSUD explore5	VF	MP NP	C5571	8	5	1

[7] Schedule 1, Part 1, entry for Amlodipine in the form Tablet 5 mg (as besilate)

omit:

Amlodipine	Tablet 5 mg (as besilate)	Oral	Norvapine	ED	MP NP			30	5	30
Amlodipine	Tablet 5 mg (as besilate)	Oral	Norvapine	ED	MP NP		P14238	60	5	30

[8] Schedule 1, Part 1, entry for Amlodipine in the form Tablet 10 mg (as besilate)

omit:

Amlodipine	Tablet 10 mg (as besilate)	Oral	Norvapine	ED	MP NP			30	5	30
Amlodipine	Tablet 10 mg (as besilate)	Oral	Norvapine	ED	MP NP		P14238	60	5	30

[9] Schedule 1, Part 1, entry for Amoxicillin with clavulanic acid in the form Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (s19A)

omit:

Amoxicillin with clavulanic acid	Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (s19A)	Oral	Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals)	QY	MP NP	C5832 C5893	P5832 P5893	10	0	20
Amoxicillin with clavulanic acid	Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (s19A)	Oral	Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals)	QY	PDP	C5833 C5894	P5833 P5894	10	0	20
Amoxicillin with clavulanic acid	Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (s19A)	Oral	Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals)	QY	MP NP	C10413	P10413	20	0	20

Amoxicillin with clavulanic acid	Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (s19A)	Oral	Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs)	QZ	MP NP	C5832 C5893	P5832 P5893	10	0	20
Amoxicillin with clavulanic acid	Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (s19A)	Oral	Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs)	QZ	PDP	C5833 C5894	P5833 P5894	10	0	20
Amoxicillin with clavulanic acid	Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (s19A)	Oral	Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs)	QZ	MP NP	C10413	P10413	20	0	20

[10] Schedule 1, Part 1, entry for Capecitabine

omit:

Capecitabine	Tablet 150 mg	Oral	Capecitabine-DRLA	RZ	MP			60	2	60

[11] Schedule 1, Part 1, omit entries for Carbomer 974

[12] Schedule 1, Part 1, entry for Cefalexin

omit:

Cefalexin	Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL (s19A)	Oral	Keforal	QY	PDP			1	0	1
Cefalexin	Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL (s19A)	Oral	Keforal	QY	MP NP			1	1	1

[13] Schedule 1, Part 1, entry for Cefuroxime

omit:

Cefuroxime	Powder for oral suspension 125 mg (as axetil) per 5 mL, 100 mL	Oral	Zinnat	AS	PDP		1	0	1
Cefuroxime	Powder for oral suspension 125 mg (as axetil) per 5 mL, 100 mL	Oral	Zinnat	AS	MP		1	1	1

[14] Schedule 1, Part 1, entry for Cemiplimab in the form Solution concentrate for I.V. infusion 350 mg in 7 mL

(a) *omit from the column headed "Responsible Person" (all instances):* **SW** *substitute (all instances):* **WM**

(b) *omit from the column headed "Circumstances":* **C13322**

(c) *omit from the column headed "Purposes":* **P13322**

[15] Schedule 1, Part 1, after entry for Colchicine in the form Tablet 500 micrograms *[Brand: Lengout; Maximum Quantity: 30; Number of Repeats: 5]*

insert:

Colestyramine	Powder for oral suspension 4 g (S19A)	Oral	Cholestyramine (Ascend, USA)	CR	MP NP		120	5	60
Colestyramine	Powder for oral suspension 4 g (S19A)	Oral	Cholestyramine (Ascend, USA)	CR	MP	P6429	120	11	60

[16] Schedule 1, Part 1, after entry for Dabigatran etexilate in the form Capsule 75 mg (as mesilate) *[Brand: ARX-Dabigatran; Maximum Quantity: 60; Number of Repeats: 0]*

insert:

Dabigatran etexilate	Capsule 75 mg (as mesilate)	Oral	PHARMACOR DABIGATRAN	CR	MP NP	C4381	P4381	20	0	10
Dabigatran etexilate	Capsule 75 mg (as mesilate)	Oral	PHARMACOR DABIGATRAN	CR	MP NP	C4369	P4369	20	1	10
Dabigatran etexilate	Capsule 75 mg (as mesilate)	Oral	PHARMACOR DABIGATRAN	CR	MP NP	C4402	P4402	60	0	60

[17] Schedule 1, Part 1, after entry for Dabigatran etexilate in the form Capsule 110 mg (as mesilate) *[Brand: Dabigatran Sandoz; Maximum Quantity: 120; Number of Repeats: 5]*

insert:

Dabigatran etexilate	Capsule 110 mg (as mesilate)	Oral	PHARMACOR DABIGATRAN	CR	MP NP	C4381	P4381	20	0	10
Dabigatran etexilate	Capsule 110 mg (as mesilate)	Oral	PHARMACOR DABIGATRAN	CR	MP NP	C4369	P4369	20	1	10
Dabigatran etexilate	Capsule 110 mg (as mesilate)	Oral	PHARMACOR DABIGATRAN	CR	MP NP	C4402	P4402	60	0	60
Dabigatran etexilate	Capsule 110 mg (as mesilate)	Oral	PHARMACOR DABIGATRAN	CR	MP NP	C4269	P4269	60	5	60
Dabigatran etexilate	Capsule 110 mg (as mesilate)	Oral	PHARMACOR DABIGATRAN	CR	MP NP	C14308	P14308	120	5	60

[18] Schedule 1, Part 1, after entry for Dabigatran etexilate in the form Capsule 150 mg (as mesilate) *[Brand: Dabigatran Sandoz; Maximum Quantity: 120; Number of Repeats: 5]*

insert:

Dabigatran etexilate	Capsule 150 mg (as mesilate)	Oral	PHARMACOR DABIGATRAN	CR	MP NP	C4269	P4269	60	5	60
Dabigatran etexilate	Capsule 150 mg (as mesilate)	Oral	PHARMACOR DABIGATRAN	CR	MP NP	C14308	P14308	120	5	60

[19] Schedule 1, Part 1, entry for Daratumumab in the form Solution concentrate for I.V. infusion 100 mg in 5 mL

omit:

Daratumumab	Solution concentrate for I.V. infusion 100 mg in 5 mL	Injection	Darzalex	JC	MP	C12844	P12844	See Note 3	See Note 3	1	PB(100)

[20] Schedule 1, Part 1, entry for Daratumumab in the form Solution concentrate for I.V. infusion 400 mg in 20 mL

omit:

Daratumumab	Solution concentrate for I.V.	Injection	Darzalex	JC	MP	C12844	P12844	See Note	See Note	1	PB(100)

	infusion 400 mg in 20 mL							3	3		

[21] **Schedule 1, Part 1, entry for Daratumumab in the form Solution for subcutaneous injection containing daratumumab 1800 mg in 15 mL *[Maximum Quantity: 1; Number of Repeats: 15]***

(a) *omit from the column headed "Circumstances":* **C13944**

(b) *omit from the column headed "Purposes":* **P13944**

[22] **Schedule 1, Part 1, after entry for Dicloxacillin in the form Capsule 500 mg (as sodium) *[Brand: Distaph 500; Maximum Quantity: 48; Number of Repeats: 1]***

insert:

Difelikefalin	Solution for I.V. injection 50 micrograms (as acetate) in 1 mL	Injection	Korsuva	CS	MP	See Note 3	See Note 3	See Note 3	See Note 3	12	D(100)

[23] **Schedule 1, Part 1, after entry for Dorzolamide with timolol in the form Eye drops containing dorzolamide 20 mg (as hydrochloride) with timolol 5 mg (as maleate) per mL, 5 mL *[Brand: Vizo-PF Dorzolatim; Authorised Prescriber: MP; Maximum Quantity: 1; Number of Repeats: 5]***

insert:

Dostarlimab	Solution concentrate for I.V. infusion 500 mg in 10 mL	Injection	Jemperli	GK	MP	C15163	P15163	See Note 3	See Note 3	1	D(100)
Dostarlimab	Solution concentrate for I.V. infusion 500 mg in 10 mL	Injection	Jemperli	GK	MP	C15196 C15205	P15196 P15205	See Note 3	See Note 3	1	D(100)

[24] **Schedule 1, Part 1, entry for Etanercept in the form Injection 50 mg in 1 mL single use auto-injector, 4 *[Brand: Brenzys; Maximum Quantity: 1; Number of Repeats: 3]***

insert in the column headed "Purposes": **P9064 P11107 P13532 P13533 P13538 P13593 P13598 P13646 P13647 P14382 P14427 P14483 P14486 P14488 P14498 P14581 P14582 P14603 P14655 P14662 P14670 P14671 P14673 P14703**

[25] **Schedule 1, Part 1, entry for Etanercept in the form Injection 50 mg in 1 mL single use auto-injector, 4 *[Brand: Brenzys; Maximum Quantity: 1; Number of Repeats: 5]***

insert in the column headed "Purposes": **P7289 P8839 P8842 P8873 P8879 P8887 P8955 P9081 P9123 P9140 P9156 P9162 P14493 P14499 P14507 P14629 P14656 P14683 P14701 P14713 P14715**

[26] **Schedule 1, Part 1, entry for Etanercept in the form Injections 50 mg in 1 mL single use pre-filled syringes, 4 *[Brand: Enbrel; Maximum Quantity: 1; Number of Repeats: 3]***

(a) *insert in numerical order in the column headed "Purposes":* **P9386 P9388 P9473**

(b) *insert in numerical order in the column headed "Purposes":* **P12164 P12261**

(c) *insert in numerical order in the column headed "Purposes":* **P14513 P14552 P14553 P14554 P14576 P14577**

(d) *omit from the column headed "Purposes":* **P14581 P14582 P14603**

(e) *insert in numerical order in the column headed "Purposes":* **P14600**

(f) *omit from the column headed "Purposes":* **P14671 P14673**

[27] **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 "Circumstances":* **C15077**

(b) *omit from the column headed "Circumstances":* **C15080**

(c) *insert in numerical order in the column headed "Circumstances":* **C15177 C15201**

(d) *omit from the column headed "Purposes":* **P15077**

(e) *omit from the column headed "Purposes":* **P15080**

(f) *insert in numerical order in the column headed "Purposes":* **P15177 P15201**

[28] **Schedule 1, Part 1, entry for Evolocumab in the form Injection 420 mg in 3.5 mL single use pre-filled cartridge**

(a) *omit from the column headed "Circumstances":* **C15077**

(b) *omit from the column headed "Circumstances":* **C15080**

(c) *insert in numerical order in the column headed "Circumstances":* **C15177 C15201**

[29] **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) *omit from the column headed "Circumstances":* **C13762**

(b) *omit from the column headed "Purposes":* **P13762**

[30] 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: 5]*

(a) *omit from the column headed "Circumstances":* **C13770**

(b) *omit from the column headed "Purposes":* **P13770**

[31] Schedule 1, Part 1, entry for Fluorometholone

omit:

Fluorometholone	Eye drops containing fluorometholone acetate 1 mg per mL, 5 mL	Application to the eye	Flarex	NV	AO		1	0	1
Fluorometholone	Eye drops containing fluorometholone acetate 1 mg per mL, 5 mL	Application to the eye	Flarex	NV	MP NP		1	2	1

[32] Schedule 1, Part 1, entry for Glucagon

omit:

Glucagon	Injection set containing glucagon hydrochloride 1 mg (1 I.U.) and 1 mL solvent in disposable syringe (s19A)	Injection	GlucaGen Hypokit (Germany)	DZ	PDP		1	0	1
Glucagon	Injection set containing glucagon hydrochloride 1 mg (1 I.U.) and 1 mL solvent in disposable syringe (s19A)	Injection	GlucaGen Hypokit (Germany)	DZ	MP NP		1	1	1

[33] Schedule 1, Part 1, entry for Hypromellose with dextran

omit:

Hypromellose with dextran	Eye drops containing 3 mg hypromellose 2900 with 1 mg dextran 70 per mL, single dose units 0.4 mL, 28	Application to the eye	Bion Tears	AQ	AO	C6172	3	5	1
Hypromellose with dextran	Eye drops containing 3 mg hypromellose 2900 with 1 mg	Application to the eye	Bion Tears	AQ	MP NP	C6172	3	5	1

	dextran 70 per mL, single dose units 0.4 mL, 28									

[34] Schedule 1, Part 1, after entry for Imiquimod in the form Cream 50 mg per g, 250 mg single use sachets, 12 *[Brand: APO-Imiquimod]*

insert:

Inclisiran	Injection 284 mg in 1.5 mL single use pre-filled syringe	Injection	Leqvio	NV	MP	C15065 C15110	P15065 P15110	1	0	1

[35] 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 "Circumstances":* **C15065 C15110**

(b) *insert in numerical order in the column headed "Purposes":* **P15122 P15132 P15144 P15153**

[36] Schedule 1, Part 1, after entry for Lercanidipine in the form Tablet containing lercanidipine hydrochloride 10 mg *[Brand: Zircol 10; Maximum Quantity: 56; Number of Repeats: 5]*

insert:

Lercanidipine	Tablet containing lercanidipine hydrochloride 20 mg	Oral	ARX-LERCANIDIPINE	TX	MP NP			28	5	28
Lercanidipine	Tablet containing lercanidipine hydrochloride 20 mg	Oral	ARX-LERCANIDIPINE	TX	MP NP		P14238	56	5	28

[37] Schedule 1, Part 1, after entry for Maraviroc in the form Tablet 300 mg

insert:

Mavacamten	Capsule 2.5 mg	Oral	Camzyos	BQ	MP	C15169 C15188	P15169 P15188	28	2	28
Mavacamten	Capsule 2.5 mg	Oral	Camzyos	BQ	MP	C15189 C15210	P15189 P15210	28	5	28
Mavacamten	Capsule 5 mg	Oral	Camzyos	BQ	MP	C15169 C15188	P15169 P15188	28	2	28
Mavacamten	Capsule 5 mg	Oral	Camzyos	BQ	MP	C15189 C15210	P15189 P15210	28	5	28
Mavacamten	Capsule 10 mg	Oral	Camzyos	BQ	MP	C15188	P15188	28	2	28

Mavacamten	Capsule 10 mg	Oral	Camzyos	BQ	MP	C15189 C15210	P15189 P15210	28	5	28
Mavacamten	Capsule 15 mg	Oral	Camzyos	BQ	MP	C15188	P15188	28	2	28
Mavacamten	Capsule 15 mg	Oral	Camzyos	BQ	MP	C15189 C15210	P15189 P15210	28	5	28

[38] Schedule 1, Part 1, after entry for Methotrexate in the form Tablet 2.5 mg *[Brand: Methoblastin]*

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

Methotrexate	Tablet 10 mg	Oral	Chexate	OX	MP NP			15	3	15

[39] Schedule 1, Part 1, entry for Methotrexate in the form Tablet 10 mg *[Brand: Chexate; Maximum Quantity: 50; Number of Repeats: 2]*

insert in the column headed "Purposes": **P5648**

[40] Schedule 1, Part 1, entry for Minoxidil

omit:

Minoxidil	Tablet 10 mg (s19A)	Oral	Minoxidil 10 mg (Roma Pharmaceuticals)	OJ	MP NP	C5177		100	5	60

[41] Schedule 1, Part 1, entry for Morphine in each of the forms: Oral solution containing morphine hydrochloride trihydrate 2 mg per mL, 1 mL; Oral solution containing morphine hydrochloride trihydrate 5 mg per mL, 1 mL; and Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL

omit from the column headed "Responsible Person" (all instances): **MF** *substitute (all instances):* **XT**

[42] Schedule 1, Part 1, entry for Niraparib in the form Capsule 100 mg (as tosilate monohydrate) *[Maximum Quantity: 56; Number of Repeats: 2]*

(a) *omit from the column headed "Circumstances":* **C15084 C15109** *substitute:* **C15230 C15239**

(b) *omit from the column headed "Purposes":* **P15084 P15109** *substitute:* **P15230 P15239**

[43] Schedule 1, Part 1, entry for Niraparib in the form Capsule 100 mg (as tosilate monohydrate) *[Maximum Quantity: 56; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C15131**

(b) *insert in numerical order in the column headed "Circumstances":* **C15203**

(c) *omit from the column headed "Purposes":* **P15131**

(d) *insert in numerical order in the column headed "Purposes":* **P15203**

[44] Schedule 1, Part 1, entry for Niraparib in the form Capsule 100 mg (as tosilate monohydrate) *[Maximum Quantity: 84; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C15142**

(b) *insert in numerical order in the column headed "Circumstances":* **C15181**

(c) *omit from the column headed "Purposes":* **P15142**

(d) *insert in numerical order in the column headed "Purposes":* **P15181**

[45] Schedule 1, Part 1, entry for Ondansetron in the form Syrup 4 mg (as hydrochloride dihydrate) per 5 mL, 50 mL *[Maximum Quantity: 1; Number of Repeats: 1]*

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[46] Schedule 1, Part 1, entry for Ondansetron in the form Tablet 4 mg (as hydrochloride dihydrate) *[Brand: APO-Ondansetron; Maximum Quantity: 10; Number of Repeats: 1]*

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[47] Schedule 1, Part 1, entry for Ondansetron in the form Tablet 4 mg (as hydrochloride dihydrate) *[Brand: APX-Ondansetron; Maximum Quantity: 10; Number of Repeats: 1]*

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[48] Schedule 1, Part 1, entry for Ondansetron in the form Tablet 4 mg (as hydrochloride dihydrate) *[Brand: Ondansetron Mylan Tablets; Maximum Quantity: 10; Number of Repeats: 1]*

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[49] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet 4 mg (as hydrochloride dihydrate)** ***[Brand: Ondansetron SZ; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[50] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet 4 mg (as hydrochloride dihydrate)** ***[Brand: Ondansetron-DRLA; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[51] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet 4 mg (as hydrochloride dihydrate)** ***[Brand: Zofran; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[52] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet 4 mg (as hydrochloride dihydrate)** ***[Brand: Zotren 4; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[53] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet 8 mg (as hydrochloride dihydrate)** ***[Brand: APO-Ondansetron; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[54] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet 8 mg (as hydrochloride dihydrate)** ***[Brand: APX-Ondansetron; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[55] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet 8 mg (as hydrochloride dihydrate) *[Brand: Ondansetron Mylan Tablets; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[56] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet 8 mg (as hydrochloride dihydrate) *[Brand: Ondansetron SZ; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[57] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet 8 mg (as hydrochloride dihydrate) *[Brand: Ondansetron-DRLA; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[58] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet 8 mg (as hydrochloride dihydrate) *[Brand: Zofran; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[59] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet 8 mg (as hydrochloride dihydrate) *[Brand: Zotren 8; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[60] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg *[Brand: APX-Ondansetron ODT; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[61] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg *[Brand: Ondansetron Mylan ODT; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[62] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg *[Brand: Ondansetron ODT Lupin; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[63] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg *[Brand: Ondansetron ODT-DRLA; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[64] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg *[Brand: Ondansetron SZ ODT; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[65] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg *[Brand: Zotren ODT; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[66] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg *[Brand: APX-Ondansetron ODT; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[67] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg *[Brand: Ondansetron Mylan ODT; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[68] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg *[Brand: Ondansetron ODT Lupin; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[69] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg *[Brand: Ondansetron ODT-DRLA; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[70] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg *[Brand: Ondansetron SZ ODT; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[71] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg *[Brand: Zotren ODT; Maximum Quantity: 10; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C15115** *substitute:* **C15193**

(b) *omit from the column headed "Purposes":* **P15115** *substitute:* **P15193**

[72] **Schedule 1, Part 1, entry for Ondansetron in each of the forms: Wafer 4 mg; and Wafer 8 mg**

omit from the column headed "Circumstances": **C15115** *substitute:* **C15193**

[73] **Schedule 1, Part 1, entry for Palbociclib in each of the forms: Tablet 75 mg; Tablet 100 mg; and Tablet 125 mg**

omit from the column headed "Circumstances": **C13055 C13066** *substitute:* **C15167 C15184**

[74] Schedule 1, Part 1, entry for Perampanel in the form Tablet 4 mg (as hemisesquihydrate)

omit:

Perampanel	Tablet 4 mg (as hemisesquihydrate)	Oral	Fycompa	EI	MP NP	C14847	P14847	56	2	28

[75] Schedule 1, Part 1, entry for Perampanel in the form Tablet 4 mg (as hemisesquihydrate) *[Maximum Quantity: 56; Number of Repeats: 5]*

(a) *insert in numerical order in the column headed "Circumstances":* **C14847**

(b) *insert in numerical order in the column headed "Purposes":* **P14847**

[76] Schedule 1, Part 1, entry for Perampanel in the form Tablet 6 mg (as hemisesquihydrate)

omit:

Perampanel	Tablet 6 mg (as hemisesquihydrate)	Oral	Fycompa	EI	MP NP	C14847	P14847	56	2	28

[77] Schedule 1, Part 1, entry for Perampanel in the form Tablet 6 mg (as hemisesquihydrate) *[Maximum Quantity: 56; Number of Repeats: 5]*

(a) *insert in numerical order in the column headed "Circumstances":* **C14847**

(b) *insert in numerical order in the column headed "Purposes":* **P14847**

[78] Schedule 1, Part 1, omit entries for Procaine benzylpenicillin

[79] Schedule 1, Part 1, after entry for Prochlorperazine in the form Tablet containing prochlorperazine maleate 5 mg *[Brand: Stemetil; Authorised Prescriber: PDP; Maximum Quantity: 25; Number of Repeats: 0]*

insert:

Prochlorperazine	Tablet containing prochlorperazine maleate 5 mg (S19A)	Oral	Stemetil (Ireland)	OJ	PDP MP NP			25	0	250

[80] Schedule 1, Part 1, entry for Ribociclib in the form Tablet 200 mg *[Maximum Quantity: 21; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C13099 C13105** *substitute:* **C15233 C15242**

(b) *omit from the column headed "Purposes":* **P13099 P13105** *substitute:* **P15233 P15242**

[81] **Schedule 1, Part 1, entry for Ribociclib in the form Tablet 200 mg *[Maximum Quantity: 42; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C13037 C13074** *substitute:* **C15165 C15209**

(b) *omit from the column headed "Purposes":* **P13037 P13074** *substitute:* **P15165 P15209**

[82] **Schedule 1, Part 1, entry for Ribociclib in the form Tablet 200 mg *[Maximum Quantity: 63; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C13084 C13093** *substitute:* **C15164 C15206**

(b) *omit from the column headed "Purposes":* **P13084 P13093** *substitute:* **P15164 P15206**

[83] **Schedule 1, Part 1, entry for Risankizumab**

omit:

Risankizumab	Injection 75 mg in 0.83 mL pre-filled syringe	Injection	Skyrizi	VE	MP	C6696 C9933 C9955	P6696 P9933 P9955	2	1	2
Risankizumab	Injection 75 mg in 0.83 mL pre-filled syringe	Injection	Skyrizi	VE	MP	C10802 C10853 C11120 C11124 C11171 C14440 C14454	P10802 P10853 P11120 P11124 P11171 P14440 P14454	2	2	2

[84] **Schedule 1, Part 1, after entry for Ripretinib in the form Tablet 50 mg**

insert:

Risankizumab	Injection 150 mg in 1 mL pre-filled pen	Injection	Skyrizi	VE	MP	C6696 C15190 C15223	P6696 P15190 P15223	1	1	1
Risankizumab	Injection 150 mg in 1 mL pre-filled pen	Injection	Skyrizi	VE	MP	C15199 C15213 C15221 C15222 C15229 C15236 C15237	P15199 P15213 P15221 P15222 P15229 P15236 P15237	1	2	1

[85] **Schedule 1, Part 1, entry for Risperidone in the form Tablet 4 mg**

omit:

Risperidone	Tablet 4 mg	Oral	Risperidone generichealth	GQ	MP NP	C4246 C5907	P4246 P5907	60	5	60

[86] Schedule 1, Part 1, after entry for Sumatriptan in the form Tablet 50 mg (as succinate) *[Brand: Pharmacor Sumatriptan 50]*

insert:

Sumatriptan	Tablet 50 mg (as succinate)	Oral	Sumagraine Migraine Relief	GQ	MP NP	C5259		4	5	2

[87] Schedule 1, Part 1, after entry for Tacrolimus in the form Capsule 0.5 mg (once daily prolonged release) *[Brand: ADVAGRAF XL; Maximum Quantity: 60; Number of Repeats: 3]*

insert:

Tacrolimus	Capsule 0.5 mg (once daily prolonged release)	Oral	Tacrolimus XR Sandoz	SZ	MP			30	3	30
Tacrolimus	Capsule 0.5 mg (once daily prolonged release)	Oral	Tacrolimus XR Sandoz	SZ	MP		P14238	60	3	30

[88] Schedule 1, Part 1, after entry for Tacrolimus in the form Capsule 1 mg (once daily prolonged release) *[Brand: ADVAGRAF XL; Maximum Quantity: 120; Number of Repeats: 3]*

insert:

Tacrolimus	Capsule 1 mg (once daily prolonged release)	Oral	Tacrolimus XR Sandoz	SZ	MP			60	3	60
Tacrolimus	Capsule 1 mg (once daily prolonged release)	Oral	Tacrolimus XR Sandoz	SZ	MP		P14238	120	3	60

[89] Schedule 1, Part 1, after entry for Tacrolimus in the form Capsule 3 mg (once daily prolonged release) *[Brand: ADVAGRAF XL; Maximum Quantity: 100; Number of Repeats: 2]*

insert:

Tacrolimus	Capsule 3 mg (once daily prolonged release)	Oral	Tacrolimus XR Sandoz	SZ	MP			50	2	50
Tacrolimus	Capsule 3 mg (once daily prolonged release)	Oral	Tacrolimus XR Sandoz	SZ	MP		P14238	100	2	50

[90] Schedule 1, Part 1, after entry for Tacrolimus in the form Capsule 5 mg (once daily prolonged release) *[Brand: ADVAGRAF XL; Maximum Quantity: 60; Number of Repeats: 3]*

insert:

Tacrolimus	Capsule 5 mg (once daily prolonged release)	Oral	Tacrolimus XR Sandoz	SZ	MP			30	3	30
Tacrolimus	Capsule 5 mg (once daily prolonged release)	Oral	Tacrolimus XR Sandoz	SZ	MP		P14238	60	3	30

[91] Schedule 1, Part 1, after entry for Tadalafil in the form Tablet 20 mg *[Brand: TADALIS 20]*

insert:

Tafamidis	Capsule 61 mg	Oral	Vyndamax	PF	MP	C15088 C15157		30	5	30

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

omit:

Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg	Oral	Tenofovir Disoproxil Emtricitabine Mylan 300/200	AF	MP NP	C11143	P11143	30	2	30
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg	Oral	Tenofovir Disoproxil Emtricitabine Mylan 300/200	AF	MP NP	C6985 C6986	P6985 P6986	60	5	30

[93] Schedule 1, Part 1, entry for Tepotinib

omit from the column headed "Circumstances": **C13435**

[94] Schedule 1, Part 1, after entry for Teriparatide in the form Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled cartridge *[Maximum Quantity: 2; Number of Repeats: 5]*

insert:

Teriparatide	Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen	Injection	Teriparatide Lupin	GQ	MP	C12270 C12492		1	5	1

[95] Schedule 1, Part 1, entry for Topiramate in the form Tablet 25 mg

omit:

Topiramate	Tablet 25 mg	Oral	Topamax	JC	MP NP	C5325 C5516	P5325 P5516	60	5	60

Topiramate	Tablet 25 mg	Oral	Topamax	JC	MP NP	C14901 C14973	P14901 P14973	120	5	60

[96] Schedule 1, Part 1, entry for Topiramate in the form Tablet 50 mg

omit:

Topiramate	Tablet 50 mg	Oral	Topamax	JC	MP NP	C5325 C5516	P5325 P5516	60	5	60
Topiramate	Tablet 50 mg	Oral	Topamax	JC	MP NP	C14901 C14973	P14901 P14973	120	5	60

[97] Schedule 1, Part 1, entry for Topiramate in the form Tablet 100 mg

omit:

Topiramate	Tablet 100 mg	Oral	Topamax	JC	MP NP	C5325 C5516	P5325 P5516	60	5	60
Topiramate	Tablet 100 mg	Oral	Topamax	JC	MP NP	C14901 C14973	P14901 P14973	120	5	60

[98] Schedule 1, Part 1, entry for Topiramate in the form Tablet 200 mg

omit:

Topiramate	Tablet 200 mg	Oral	Topamax	JC	MP NP	C5516	P5516	60	5	60
Topiramate	Tablet 200 mg	Oral	Topamax	JC	MP NP	C14973	P14973	120	5	60

[99] Schedule 1, Part 1, entry for Trimethoprim in the form Tablet 300 mg

omit:

Trimethoprim	Tablet 300 mg	Oral	Trimethoprim Mylan	AL	MP NP			7	1	7
Trimethoprim	Tablet 300 mg	Oral	Trimethoprim Mylan	AL	MP		P4243	14 CN4243	2 CN4243	7
Trimethoprim	Tablet 300 mg	Oral	Trimethoprim Mylan	AL	MP		P6163	28	0	7

[100] Schedule 1, Part 1, entry for Upadacitinib in the form Tablet 15 mg *[Maximum Quantity: 28; Number of Repeats: 5]*

(a) *insert in numerical order in the column headed "Circumstances":* **C14499**

(b) *omit from the column headed "Circumstances":* **C14613 C14633**

(c) *insert in numerical order in the column headed "Circumstances":* **C15195 C15204**

(d) *insert in numerical order in the column headed "Purposes":* **P14499**

(e) *omit from the column headed "Purposes":* **P14613 P14633**

(f) *insert in numerical order in the column headed "Purposes":* **P15195 P15204**

[101] Schedule 1, Part 1, after entry for Valproic acid in the form Oral solution containing sodium valproate 200 mg per 5 mL, 300 mL *[Brand: Epilim Syrup; Maximum Quantity: 4; Number of Repeats: 2]*

insert:

Valproic acid	Tablet (enteric coated) containing sodium valproate 200 mg	Oral	APO-Sodium Valproate	TX	MP NP		200	2	100
Valproic acid	Tablet (enteric coated) containing sodium valproate 200 mg	Oral	APO-Sodium Valproate	TX	MP NP	P14238	400	2	100

[102] Schedule 1, Part 1, after entry for Valproic acid in the form Tablet (enteric coated) containing sodium valproate 200 mg *[Brand: Valproate Winthrop EC 200; Maximum Quantity: 400; Number of Repeats: 2]*

insert:

Valproic acid	Tablet (enteric coated) containing sodium valproate 500 mg	Oral	APO-Sodium Valproate	TX	MP NP		200	2	100
Valproic acid	Tablet (enteric coated) containing sodium valproate 500 mg	Oral	APO-Sodium Valproate	TX	MP NP	P14238	400	2	100

[103] Schedule 1, Part 1, entry for Vericiguat in each of the forms: Tablet 2.5 mg; and Tablet 5 mg *[Authorised Prescriber: MP]*

omit from the column headed "Circumstances": **C13621**

[104] Schedule 1, Part 1, entry for Vericiguat in the form Tablet 10 mg *[Authorised Prescriber: MP]*

omit from the column headed "Circumstances": **C13621**

[105] Schedule 1, Part 2, omit entries for Amino acid formula with vitamins and minerals without methionine *[Brands: HCU cooler 10; and HCU cooler 15]*

[106] **Schedule 1, Part 2, omit entry for Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine *[Brand: MMA/PA gel]***

[107] **Schedule 1, Part 2, omit entries for Amino acid formula with vitamins and minerals without phenylalanine and tyrosine *[Brands: TYR cooler 10; TYR cooler 15; and TYR express 15]***

[108] **Schedule 1, Part 2, omit entry for Amino acid formula with vitamins and minerals without valine, leucine and isoleucine *[Brand: MSUD cooler 10]***

[109] **Schedule 1, Part 2**

insert as first entry:

Capecitabine	Tablet 150 mg	Oral	Capecitabine-DRLA	RZ	60
Carbomer 974	Ocular lubricating gel 3 mg per g, single dose units 0.5 g, 30	Application to the eye	Poly Gel	AQ	1

[110] **Schedule 1, Part 2, after entry for Estradiol in the form Transdermal patches 7.6 mg, 4**

insert:

Fluorometholone	Eye drops containing fluorometholone acetate 1 mg per mL, 5 mL	Application to the eye	Flarex	NV	1
Hypromellose with dextran	Eye drops containing 3 mg hypromellose 2900 with 1 mg dextran 70 per mL, single dose units 0.4 mL, 28	Application to the eye	Bion Tears	AQ	1

[111] **Schedule 1, Part 2, after entry for Raltegravir in the form Tablet 100 mg (as potassium)**

insert:

Risankizumab	Injection 75 mg in 0.83 mL pre-filled syringe	Injection	Skyrizi	VE	2

[112] **Schedule 3**

omit:

ED	Amneal Pharmaceuticals Pty Ltd	21 147 854 484

[113] **Schedule 3**

omit:

QZ	Pro Pharmaceuticals Group Pty. Ltd.	20 605 457 430

[114] Schedule 4, Part 1, entry for Circumstances Code "C5533"

insert in alphabetical order in the column headed "Listed Drug": **Amino acid formula with vitamins and minerals, without phenylalanine, tyrosine and supplemented with arachidonic acid and docosahexaenoic acid**

[115] Schedule 4, Part 1, entry for Circumstances Code "C5534"

insert in alphabetical order in the column headed "Listed Drug": **Amino acid formula with vitamins and minerals without methionine and supplemented with arachidonic acid and docosahexaenoic acid**

[116] Schedule 4, Part 1, entry for Circumstances Code "C5571"

insert in alphabetical order in the column headed "Listed Drug": **Amino acid formula with vitamins and minerals without valine, leucine, isoleucine and supplemented with arachidonic acid and docosahexaenoic acid**

[117] Schedule 4, Part 1, entry for Circumstances Code "C6172"

(a) *omit from the column headed "Listed Drug":* **Carbomer 974**

(b) *omit from the column headed "Listed Drug":* **Hypromellose with dextran**

[118] Schedule 4, Part 1, omit entry for Circumstances Code "C9933"

[119] Schedule 4, Part 1, omit entry for Circumstances Code "C9955"

[120] Schedule 4, Part 1, entry for Circumstances Code "C10802"

omit from the column headed "Listed Drug": **Risankizumab**

[121] Schedule 4, Part 1, entry for Circumstances Code "C10853"

omit from the column headed "Listed Drug": **Risankizumab**

[122] Schedule 4, Part 1, entry for Circumstances Code "C11120"

omit from the column headed "Listed Drug": **Risankizumab**

[123] Schedule 4, Part 1, omit entry for Circumstances Code "C11124"

[124] Schedule 4, Part 1, omit entry for Circumstances Code "C11171"

[125] Schedule 4, Part 1, omit entry for Circumstances Code "C12844"

[126] Schedule 4, Part 1, omit entry for Circumstances Code "C13035"

[127] **Schedule 4, Part 1, omit entry for Circumstances Code "C13036"**

[128] **Schedule 4, Part 1, omit entry for Circumstances Code "C13037"**

[129] **Schedule 4, Part 1, omit entry for Circumstances Code "C13055"**

[130] **Schedule 4, Part 1, omit entry for Circumstances Code "C13066"**

[131] **Schedule 4, Part 1, omit entry for Circumstances Code "C13074"**

[132] **Schedule 4, Part 1, omit entry for Circumstances Code "C13084"**

[133] **Schedule 4, Part 1, omit entry for Circumstances Code "C13093"**

[134] **Schedule 4, Part 1, omit entry for Circumstances Code "C13099"**

[135] **Schedule 4, Part 1, omit entry for Circumstances Code "C13105"**

[136] **Schedule 4, Part 1, omit entry for Circumstances Code "C13322"**

[137] **Schedule 4, Part 1, omit entry for Circumstances Code "C13400"**

[138] **Schedule 4, Part 1, omit entry for Circumstances Code "C13435"**

[139] **Schedule 4, Part 1, omit entry for Circumstances Code "C13492"**

[140] **Schedule 4, Part 1, omit entry for Circumstances Code "C13580"**

[141] **Schedule 4, Part 1, omit entry for Circumstances Code "C13621"**

[142] **Schedule 4, Part 1, omit entry for Circumstances Code "C13658"**

[143] **Schedule 4, Part 1, omit entry for Circumstances Code "C13671"**

[144] **Schedule 4, Part 1, omit entry for Circumstances Code "C13762"**

[145] **Schedule 4, Part 1, omit entry for Circumstances Code "C13770"**

[146] **Schedule 4, Part 1, omit entry for Circumstances Code "C13944"**

[147] **Schedule 4, Part 1, omit entry for Circumstances Code "C14440"**

[148] **Schedule 4, Part 1, omit entry for Circumstances Code "C14454"**

[149] **Schedule 4, Part 1, entry for Circumstances Code "C14499"**

insert in alphabetical order in the column headed "Listed Drug": **Upadacitinib**

[150] Schedule 4, Part 1, omit entry for Circumstances Code "C14613"

[151] Schedule 4, Part 1, omit entry for Circumstances Code "C14633"

[152] Schedule 4, Part 1, omit entry for Circumstances Code "C15077"

[153] Schedule 4, Part 1, omit entry for Circumstances Code "C15080"

[154] Schedule 4, Part 1, omit entry for Circumstances Code "C15084"

[155] Schedule 4, Part 1, after entry for Circumstances Code "C15085"

insert:

C15088	P15088	CN15088	Tafamidis	Transthyretin amyloid cardiomyopathy Second and subsequent PBS-subsidised prescriptions for this drug Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have an estimated glomerular filtration rate (eGFR) greater than 25 mL/minute/1.73 m2; AND The treatment must be ceased where the patient's heart failure has worsened to persistent New York Heart Association (NYHA) Class III/IV heart failure; AND The treatment must be ceased where the patient has received any of: (i) a heart transplant, (ii) a liver transplant, (iii) an implanted ventricular assist device. Must be treated by a medical practitioner who is any of the following: (i) a cardiologist, (ii) a consultant physician with experience in the management of amyloid disorders; this authority application must be sought by the same medical practitioner providing treatment. Confirm whether heart failure has worsened to NYHA Class III/IV since the last authority application (yes/no). If 'no', continued PBS subsidy is available. If 'yes', continued PBS subsidy is available, but the prescriber must undertake a review of the patient within 3 months to determine whether the worsening heart failure was transient or persistent. Prescribe no more than 2 repeat prescriptions in such an instance. Where this subsequent clinical review finds that the heart failure persists as NYHA Class III/IV heart failure despite active treatment with this drug, then PBS subsidy is not available.	Compliance with Authority Required procedures

[156] Schedule 4, Part 1, omit entry for Circumstances Code "C15109"

[157] Schedule 4, Part 1, omit entry for Circumstances Code "C15115"

[158] Schedule 4, Part 1, omit entry for Circumstances Code "C15131"

[159] Schedule 4, Part 1, omit entry for Circumstances Code "C15142"

[160] Schedule 4, Part 1, after entry for Circumstances Code "C15155"

insert:

C15157	P15157	CN15157	Tafamidis	Transthyretin amyloid cardiomyopathy First PBS-subsidised prescription for this drug The treatment must be for wild-type transthyretin-mediated amyloid cardiomyopathy, with documented evidence of transthyretin precursor protein present; OR The treatment must be for variant transthyretin-mediated (also known as hereditary transthyretin-mediated) amyloid cardiomyopathy, with documented evidence of transthyretin precursor protein present; AND Patient must have experienced at least one episode of hospitalisation that was a direct result of heart failure; OR Patient must have clinical evidence of heart failure without hospitalisation that required treatment with a diuretic for improvement; AND Patient must have/have had New York Heart Association class I heart failure at the time of commencing this drug; OR Patient must have/have had New York Heart Association class II heart failure at the time of commencing this drug; AND Patient must have an end-diastolic interventricular septal wall thickness of at least 12 mm on imaging; AND Patient must have an estimated glomerular filtration rate (eGFR) greater than 25 mL/minute/1.73 m2. Must be treated by a medical practitioner who is any of the following: (i) a cardiologist, (ii) a consultant physician with experience in the management of amyloid disorders; this authority application must be sought by the same medical practitioner providing treatment. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; 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). Evidence of clinical findings to establish the diagnosis:	Compliance with Authority Required procedures

				In this authority application, confirm that there is documented evidence of transthyretin precursor protein through either (1) alone, or, both (2) and (3), from the list below: Confirm the following has been completed: (1) amyloid expert centre histology findings derived via immunohistochemistry or mass spectrometry; OR (2) bone scintigraphy with grade 2-3 finding AND (3) Confirm that there are negative results for monoclonal protein on each of the following three tests: (a) serum immunofixation (also known as protein electrophoresis) (b) urine immunofixation (c) serum free light chains blood test State which of (1) to (3) above has been completed, as well as the: (i) date of the finding, (ii) imaging/pathology report number/code that links the finding to the patient, (iii) name of the amyloid expert centre in this authority application. For end-diastolic interventricular septal wall thickness (at least 12 mm), confirm that: (i) imaging (echocardiogram or magnetic resonance imaging) has been undertaken; and (ii) that the imaging report is stored in the patient's medical records. State the date that the imaging was performed and the thickness (in mm) in this authority application. Where this authority application is to transition a patient from non-PBS-subsidised to PBS-subsidised supply (i.e. a 'grandfathered' patient), confirm the following: (i) the patient's heart failure has not worsened to persistent New York Heart Association Class III/IV heart failure while taking this drug.	

[161] Schedule 4, Part 1, after entry for Circumstances Code "C15162"

insert:

C15163	P15163	CN15163	Dostarlimab	Advanced, metastatic or recurrent endometrial carcinoma Initial treatment covering the first 6 treatment cycles Patient must have deficient mismatch repair (dMMR) endometrial cancer, as determined by immunohistochemistry test; AND The condition must be unsuitable for at least one of the following: (i) curative surgical resection, (ii) curative radiotherapy; AND	Compliance with Authority Required procedures - Streamlined Authority Code 15163

				The treatment must be initiated in combination with platinum-containing chemotherapy; AND The condition must be, at treatment initiation with this drug, either: (i) untreated with systemic therapy, (ii) treated with neoadjuvant/adjuvant systemic therapy, but the cancer has recurred or progressed after more than 6 months from the last dose of systemic therapy; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation.	
C15164	P15164	CN15164	Ribociclib	Locally advanced or metastatic breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant; AND The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy. Patient must not be premenopausal. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	Compliance with Authority Required procedures
C15165	P15165	CN15165	Ribociclib	Locally advanced or metastatic breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant; AND The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; AND Patient must require dosage reduction requiring a pack of 42 tablets. Patient must not be premenopausal.	Compliance with Authority Required procedures

				PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C15167	P15167	CN15167	Palbociclib	Locally advanced or metastatic breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant; AND The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy. Patient must not be premenopausal. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	Compliance with Authority Required procedures
C15169	P15169	CN15169	Mavacamten	Symptomatic obstructive hypertrophic cardiomyopathy Initial treatment (covering the first 12 weeks of therapy) Patient must have confirmed left ventricular hypertrophy due to hypertrophic cardiomyopathy; AND Patient must have maximal end-diastolic left ventricular wall thickness which is at least one of either: (i) no less than 15 mm; (ii) no less than 13 mm if patient has familial hypertrophic cardiomyopathy (at least one first degree relative with a diagnosis of hypertrophic cardiomyopathy); AND Patient must have confirmed peak left ventricular outflow tract (LVOT) gradient of no less than 50 mm Hg which is measured either: (i) at rest; (ii) after provocation with at least one of (a) Valsalva manoeuvre, (b) exercise; AND Patient must have a current left ventricular ejection fraction (LVEF) of no less than 55%; AND Patient must have had prior treatments with each of a (i) beta-blocker and (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy; AND	Compliance with Written Authority Required procedures

				Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy; AND Patient must be symptomatic with NYHA classes II or III. Must be treated by a cardiologist; OR Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy. Patient must be at least 18 years of age. The authority application must be made in writing and must include all the following: (1) A completed authority prescription form; 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). (3) The details of the echocardiogram and/ or cardiac magnetic resonance imaging (MRI) report confirming the diagnosis of hypertrophic cardiomyopathy (HCM). State all the following: (a) the date, unique identifying number/code or provider number of the report; (b) the left ventricular wall thickness in millimetres (mm). (4) The details of a genotyping test report if the patient had been tested. State all the following: (a) the date, unique identifying number/code or provider number of the report; (b) if a gene has been identified that is associated with HCM; (c) if any first-degree family relative has a confirmed diagnosis of HCM. (5) The details of the LVOT gradient report. State all the following: (a) the date, unique identifying number/code or provider number of the report; (b) the measured LVOT gradient; (c) how the LVOT gradient was measured (rest, Valsalva manoeuvre or exercise). (6) NYHA status. (7) The current beta-blocker or non-dihydropyridine calcium channel blocker (either diltiazem or verapamil only) therapy if applicable. (8) Prior beta-blocker or non-dihydropyridine calcium channel blocker trials, including: (a) if the patient is currently taking beta-blocker therapy, state the previous therapy with non-dihydropyridine calcium channel blocker that was trialled confirming that it was not effective;	

				(b) if the patient is currently taking non-dihydropyridine calcium channel blocker therapy, state the previous therapy with beta-blocker that was trialled confirming that it was not effective; (c) if there is contraindication or intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information, specify the details. All results and reports must be documented in the patient's medical records.	
C15177	P15177	CN15177	Alirocumab 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.	Compliance with Authority Required procedures - Streamlined Authority Code 15177
C15181	P15181	CN15181	Niraparib	High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer Continuation of first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 capsules The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial first-line maintenance therapy (BRCA1/2 gene mutation); AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.	Compliance with Authority Required procedures
C15184	P15184	CN15184	Palbociclib	Locally advanced or metastatic breast cancer Initial treatment Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative;	Compliance with Authority Required procedures

				AND The condition must be inoperable; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with a non-steroidal aromatase inhibitor; OR The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only; AND The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy. Patient must not be premenopausal. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C15186	P15186	CN15186	Abemaciclib	Early breast cancer The treatment must be adjuvant to surgical resection; AND The condition must not have been treated with adjuvant endocrine therapy for more than 6 months prior to commencing this drug; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be hormone receptor positive; AND The condition must be at high risk of recurrence at treatment initiation with this drug, with high risk being any of: (a) cancer cells in at least 4 positive axillary lymph nodes, (b) cancer cells in 1 to 3 positive axillary lymph nodes plus at least one of: (i) tumour size of at least 5 cm in size, (ii) grade 3 tumour histology (on the Nottingham grading system); AND The treatment must not be a PBS-subsidised benefit beyond whichever comes first: (i) a total of 2 years of active treatment (this includes any non-PBS-subsidised supply if applicable), (ii) disease recurrence/progression; AND The treatment must not be in combination with any of the following: (i) olaparib, (ii) pembrolizumab. Patient must be undergoing concurrent treatment with endocrine therapy where this drug is being prescribed as a PBS benefit. Retain all pathology imaging and investigative test results in the patient's medical records. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at	Compliance with Authority Required procedures

				any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C15188	P15188	CN15188	Mavacamten	Symptomatic obstructive hypertrophic cardiomyopathy First continuing treatment (until at least 6 months on optimal dose is achieved) Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction; OR Patient must have previously received PBS-subsidised treatment with this drug for this condition under the grandfather treatment restriction if dose titration or 6 months on optimal dose is yet to be achieved; AND Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy; AND Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%; AND Patient must be titrating mavacamten treatment until optimal dose is achieved; OR Patient must be continuing mavacamten treatment to reach at least 6 months on the optimal dose prior to assessing the response. Must be treated by a cardiologist; OR Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy. The assessment of response must be conducted after at least 6 months on optimal dose to determine the patient's eligibility for maintenance treatment. Where an assessment is not undertaken, the patient will not be eligible for ongoing treatment. This treatment phase listing intends to provide up to 36 weeks of treatment in 3 treatment courses. For the purposes of this restriction, an adequate response to treatment is defined as: an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) peak left ventricular outflow tract (LVOT) gradient.	Compliance with Authority Required procedures
C15189	P15189	CN15189	Mavacamten	Symptomatic obstructive hypertrophic cardiomyopathy Subsequent continuing treatment - Maintenance treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; OR Patient must have previously received PBS-subsidised treatment with this drug for this condition under the grandfather arrangements if at least 6 months on optimal dose is	Compliance with Authority Required procedures

				achieved; AND Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy; AND Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%; AND Patient must have demonstrated a response after at least 6 months on the optimal dose of mavacamten treatment defined as an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) peak left ventricular outflow tract (LVOT) gradient. Must be treated by a cardiologist; OR Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.	
C15190	P15190	CN15190	Risankizumab	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) a completed authority prescription form(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	Compliance with Written Authority Required procedures

				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 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.	
C15193	P15193	CN15193	Ondansetron	Nausea and vomiting The condition must be associated with radiotherapy being used to treat malignancy; OR The condition must be associated with chemotherapy (including methotrexate) being used in the treatment of malignancy and juvenile autoimmune conditions.	Compliance with Authority Required procedures - Streamlined Authority Code 15193
C15195	P15195	CN15195	Upadacitinib	Severe active rheumatoid arthritis First Continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. 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 Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;	Compliance with Written Authority Required procedures

				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 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). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must 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 determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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 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 has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. 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.	
C15196	P15196	CN15196	Dostarlimab	Advanced, metastatic or recurrent endometrial carcinoma Transitioning from non-PBS to PBS-subsidised treatment - Grandfather treatment Patient must have deficient mismatch repair (dMMR) endometrial cancer, as determined by immunohistochemistry test; AND	Compliance with Authority Required procedures - Streamlined Authority Code 15196

				Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024; AND The condition must be, prior to initiation of non-PBS-subsidised treatment with this drug, unsuitable for at least one of the following: (i) curative surgical resection, (ii) curative radiotherapy; AND The condition must be, prior to initiation of non-PBS-subsidised treatment with this drug, either: (i) untreated with systemic therapy, (ii) treated with neoadjuvant/adjuvant systemic therapy, but the cancer has recurred or progressed after more than 6 months from the last dose of systemic therapy; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation; AND The treatment must be, at initiation of non-PBS-subsidised treatment with this drug, used in combination with platinum-containing chemotherapy; AND Patient must not have developed disease progression while receiving non-PBS-subsidised treatment with this drug for this condition. Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 36 cumulative months from the first administered dose, once in a lifetime.	
C15199	P15199	CN15199	Risankizumab	Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (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 for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (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, Whole body (recommencement of treatment after a break in biological medicine of more 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 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in	Compliance with Authority Required procedures

				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, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; AND The treatment must be as systemic monotherapy (other than methotrexate); 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 dermatologist.	
C15201	P15201	CN15201	Alirocumab 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 15201
C15203	P15203	CN15203	Niraparib	High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer Continuation of first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.	Compliance with Authority Required procedures
C15204	P15204	CN15204	Upadacitinib	Severe active rheumatoid arthritis First Continuing treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under	Compliance with Authority Required procedures

				the first continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment.	
C15205	P15205	CN15205	Dostarlimab	Advanced, metastatic or recurrent endometrial carcinoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 36 cumulative months from the first administered dose, once in a lifetime.	Compliance with Authority Required procedures - Streamlined Authority Code 15205
C15206	P15206	CN15206	Ribociclib	Locally advanced or metastatic breast cancer Initial treatment Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only; AND The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy. Patient must not be premenopausal. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	Compliance with Authority Required procedures

C15209	P15209	CN15209	Ribociclib	Locally advanced or metastatic breast cancer Initial treatment Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only; AND The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; AND Patient must require dosage reduction requiring a pack of 42 tablets. Patient must not be premenopausal. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	Compliance with Authority Required procedures
C15210	P15210	CN15210	Mavacamten	Symptomatic obstructive hypertrophic cardiomyopathy Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024; AND Patient must have had confirmed left ventricular hypertrophy due to hypertrophic cardiomyopathy prior to commencing non-PBS-subsidised treatment; AND Patient must have had maximal end-diastolic left ventricular wall thickness, prior to commencing non-PBS-subsidised treatment, which is at least one of either: (i) no less than 15 mm; (ii) no less than 13 mm if patient has familial hypertrophic cardiomyopathy (at least one first degree relative with a diagnosis of hypertrophic cardiomyopathy); AND Patient must have had confirmed peak left ventricular outflow tract (LVOT) gradient,	Compliance with Written Authority Required procedures

				prior to commencing non-PBS-subsidised treatment, of no less than 50 mm Hg which is measured either: (i) at rest; (ii) after provocation with at least one of: (a) Valsalva manoeuvre; (b) exercise; AND Patient must have had left ventricular ejection fraction (LVEF) of no less than 55% prior to commencing non-PBS-subsidised treatment; AND Patient must have had prior treatments with each of a (i) beta-blocker and (ii) non-dihydropyridine calcium channel blocker, unless contraindication/ intolerance present, prior to commencing non-PBS-subsidised treatment; AND Patient must have been symptomatic with NYHA classes II or III prior to commencing non-PBS-subsidised treatment; AND Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy; AND Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%; AND Patient must have demonstrated a response if received the optimal dose of mavacamten treatment for at least 6 months, defined as an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) LVOT gradient; OR Patient must be receiving mavacamten treatment but have not reached at least 6 months on optimal dose to demonstrate a response as defined above. Must be treated by a cardiologist; OR Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy. Patient must be at least 18 years of age. The authority application must be made in writing and must include all the following: (1) A completed authority prescription form; 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). (3) The details of the echocardiogram and/ or cardiac magnetic resonance imaging (MRI) report confirming the diagnosis of hypertrophic cardiomyopathy (HCM). State all the following: (a) the date, unique identifying number/code or provider number of the report; (b) the left ventricular wall thickness in millimetres (mm). (4) The details of a genotyping test report if the patient had been tested. State all the	

				following: (a) the date, unique identifying number/code or provider number of the report; (b) if a gene has been identified that is associated with HCM; (c) if any first-degree family relative has a confirmed diagnosis of HCM. (5) The details of the LVOT gradient report. State all the following: (a) the date, unique identifying number/code or provider number of the report; (b) the measured LVOT gradient; (c) how the LVOT gradient was measured (rest, Valsalva manoeuvre or exercise). (6) NYHA status. (7) The current beta-blocker or non-dihydropyridine calcium channel blocker (either diltiazem or verapamil only) therapy if applicable. (8) Prior beta-blocker or non-dihydropyridine calcium channel blocker trials, including: (a) if the patient is currently taking beta-blocker therapy, state the previous therapy with non-dihydropyridine calcium channel blocker that was trialled confirming that it was not effective; (b) if the patient is currently taking non-dihydropyridine calcium channel blocker therapy, state the previous therapy with beta-blocker that was trialled confirming that it was not effective; (c) if there is contraindication or intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information, specify the details. All results and reports must be documented in the patient's medical records.	
C15213	P15213	CN15213	Risankizumab	Severe chronic plaque psoriasis Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break 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 The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist.	Compliance with Written Authority Required procedures

				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. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence 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) a completed authority prescription form(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. At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.	
C15218	P15218	CN15218	Abemaciclib	Locally advanced or metastatic breast cancer	Compliance with Authority

				Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant; AND The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy. Patient must not be premenopausal. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	Required procedures
C15219	P15219	CN15219	Abemaciclib	Locally advanced or metastatic breast cancer Initial treatment Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only; AND The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy. Patient must not be premenopausal. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	Compliance with Authority Required procedures

C15221	P15221	CN15221	Risankizumab	Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND 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, 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 28 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	Compliance with Written Authority Required procedures

				application. The authority application must be made in writing and must include: (1) a completed authority prescription form(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. At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.	
C15222	P15222	CN15222	Risankizumab	Severe chronic plaque psoriasis Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break 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 The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction.	Compliance with Written Authority Required procedures

				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 re-commence 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) a completed authority prescription form(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, and the face, hand, foot area diagrams 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. At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.	
C15223	P15223	CN15223	Risankizumab	Severe chronic plaque psoriasis Continuing treatment, Face, hand, foot 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 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 authority application must be made in writing and must include: (a) a completed authority prescription form(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 and face, hand, foot area diagrams 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. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. An application for the continuing treatment must be accompanied with the assessment	Compliance with Written Authority Required procedures

				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 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.	
C15229	P15229	CN15229	Risankizumab	Severe chronic plaque psoriasis Initial treatment - Initial 3, Whole body (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 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 a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. 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) a completed authority prescription form(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 completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition. 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.	Compliance with Written Authority Required procedures

				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.	
C15230	P15230	C15230	Niraparib	High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer Initial first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the BRCA1/2 gene(s) - this has been confirmed by a validated test; AND Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition. Patient must be undergoing treatment with this drug class for the first time; OR Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal. A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines. Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.	Compliance with Authority Required procedures
C15233	P15233	CN15233	Ribociclib	Locally advanced or metastatic breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor,	Compliance with Authority Required procedures

				(ii) fulvestrant; AND Patient must require dosage reduction requiring a pack of 21 tablets; AND The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy. Patient must not be premenopausal. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C15236	P15236	CN15236	Risankizumab	Severe chronic plaque psoriasis Initial treatment - Initial 1, Face, hand, foot (new patient) 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 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, 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 28 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	Compliance with Written Authority Required procedures

				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) 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: (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 (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, 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) a completed authority prescription form(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. At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.	
C15237	P15237	CN15237	Risankizumab	Severe chronic plaque psoriasis Initial treatment - Initial 3, Face, hand, foot (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 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 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 The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. 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) a completed authority prescription form(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 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. 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	Compliance with Written Authority Required procedures

				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.	
C15239	P15239	C15239	Niraparib	High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer Initial first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules The condition must be associated with homologous recombination deficiency (HRD) positive status defined by genomic instability, which has been confirmed by a validated test; AND The condition must not be associated with pathogenic variants (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the BRCA1/2 genes - this has been confirmed by a validated test; AND Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; OR The condition must have both: (i) been in a partial/complete response to the immediately preceding platinum-based chemotherapy regimen prior to having commenced non-PBS-subsidised treatment with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition. Patient must be undergoing treatment with this drug class for the first time; OR Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal. A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines. Evidence of homologous recombination deficiency (genomic instability) must be derived through a test that has been validated against the Myriad MyChoice HRD assay, which uses a score of 42 or greater as the threshold for HRD (genomic instability) positivity. Evidence that BRCA1/2 gene mutations are absent must also be derived through a	Compliance with Authority Required procedures

				validated test as described above.	
C15242	P15242	CN15242	Ribociclib	Locally advanced or metastatic breast cancer Initial treatment Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only; AND The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; AND Patient must require dosage reduction requiring a pack of 21 tablets. Patient must not be premenopausal. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	Compliance with Authority Required procedures

[162] Schedule 5, entry for Acarbose in the form Tablet 100 mg

omit from the column headed "Brand": **Acarbse Viatris** *substitute:* **Acarbose Viatris**

[163] Schedule 5, entry for Amlodipine in the form Tablet 10 mg (as besilate)

omit from the column headed "Brand": **Norvapine**

[164] Schedule 5, entry for Amlodipine in the form Tablet 5 mg (as besilate)

omit from the column headed "Brand": **Norvapine**

[165] **Schedule 5, entry for Amoxicillin with clavulanic acid in the form Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (s19A)**

(a) *omit from the column headed "Brand":* **Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Pro Pharmaceuticals)**

(b) *omit from the column headed "Brand":* **Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs)**

[166] **Schedule 5, entry for Baclofen in the form Tablet 10 mg**

omit from the column headed "Brand": **APO-Baclofenx** *substitute:* **APO-Baclofen**

[167] **Schedule 5, entry for Carbamazepine in the form Tablet 100 mg**

omit from the column headed "Brand": **Tegretol 200** *substitute:* **Tegretol 100**

[168] **Schedule 5, entry for Carvedilol in the form Tablet 6.25 mg**

omit from the column headed "Brand": **APO-Carvedilo** *substitute:* **APO-Carvedilol**

[169] **Schedule 5, entry for Cefalexin**

omit:

Cefalexin	GRP-27406	Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL (s19A)	Oral	Keforal

[170] **Schedule 5, omit entry for Cetirizine hydrochloride**

[171] **Schedule 5, entry for Dabigatran etexilate in each of the forms: Capsule 110 mg (as mesilate); Capsule 150 mg (as mesilate); and Capsule 75 mg (as mesilate)**

insert in alphabetical order in the column headed "Brand": **PHARMACOR DABIGATRAN**

[172] **Schedule 5, entry for Deferasirox in the form Tablet 360 mg**

omit from the column headed "Schedule Equivalent Group": **GRP- 25395** *substitute:* **GRP-25395**

[173] **Schedule 5, omit entry for Docusate with sennoside B**

[174] **Schedule 5, entry for Epoprostenol in the form Powder for I.V. infusion 1.5 mg (as sodium)**

omit from the column headed "Schedule Equivalent Group": **GRP-16976** *substitute:* **GRP-28614**

[175] **Schedule 5, entry for Epoprostenol in the form Powder for I.V. infusion 1.5 mg (as sodium) with 2 vials diluent 50 mL**

omit from the column headed "Schedule Equivalent Group": **GRP-16976** *substitute:* **GRP-28614**

[176] **Schedule 5, entry for Epoprostenol in the form Powder for I.V. infusion 500 micrograms (as sodium)**

omit from the column headed "Schedule Equivalent Group": **GRP-16914** *substitute:* **GRP-28616**

[177] **Schedule 5, entry for Epoprostenol in the form Powder for I.V. infusion 500 micrograms (as sodium) with 2 vials diluent 50 mL**

omit from the column headed "Schedule Equivalent Group": **GRP-16914** *substitute:* **GRP-28616**

[178] **Schedule 5, entry for Ezetimibe**

omit from the column headed "Brand": **EZEMICHO** *substitute:* **EZEMICHOL**

[179] **Schedule 5, omit entry for Glucagon**

[180] **Schedule 5, entry for Lercanidipine in the form Tablet containing lercanidipine hydrochloride 20 mg**

insert in alphabetical order in the column headed "Brand": **ARX-LERCANIDIPINE**

[181] **Schedule 5, entry for Levetiracetam in the form Tablet 500 mg**

omit from the column headed "Brand": **Kevtam500** *substitute:* **Kevtam 500**

[182] **Schedule 5, entry for Memantine in the form Tablet containing memantine hydrochloride 10 mg**

omit from the column headed "Schedule Equivalent Group": **GRP-19971** *substitute:* **GRP-20090**

[183] **Schedule 5, entry for Memantine in the form Tablet containing memantine hydrochloride 20 mg**

omit from the column headed "Schedule Equivalent Group": **GRP-20090** *substitute:* **GRP-19971**

[184] **Schedule 5, entry for Methylprednisolone in the form Cream containing methylprednisolone aceponate 1 mg per g, 15 g**

omit from the column headed "Schedule Equivalent Group": **GRP-15597** *substitute:* **GRP-27997**

[185] **Schedule 5, entry for Metoprolol in each of the forms: Tablet containing metoprolol tartrate 100 mg; and Tablet containing metoprolol tartrate 50 mg**

omit from the column headed "Brand": **Mistrom**

[186] **Schedule 5, omit entry for Minoxidil**

[187] **Schedule 5, entry for Octreotide in the form Injection 100 micrograms (as acetate) in 1 mL**

omit from the column headed "Schedule Equivalent Group": **GRP-20082** *substitute:* **GRP-20282**

[188] Schedule 5, entry for Paracetamol in the form Tablet 665 mg (modified release)

(a) *omit from the column headed "Schedule Equivalent Group":* **GRP-20410** *substitute:* **GRP-20761**

(b) *omit from the column headed "Brand":* **Pharmacy Action Paracetamol Osteo 665**

[189] Schedule 5, entry for Prochlorperazine in the form Tablet containing prochlorperazine maleate 5 mg

omit from the column headed "Schedule Equivalent Group": **GRP-20123** *substitute:* **GRP-28600**

[190] Schedule 5, after entry for Prochlorperazine in the form Tablet containing prochlorperazine maleate 5 mg

insert:

Prochlorperazine	GRP-28600	Tablet containing prochlorperazine maleate 5 mg (S19A)	Oral	Stemetil (Ireland)

[191] Schedule 5, entry for Risperidone in the form Tablet 4 mg

omit from the column headed "Brand": **Risperidone generichealth**

[192] Schedule 5, entry for Sildenafil

omit from the column headed "Schedule Equivalent Group": **GRP-19585** *substitute:* **GRP-20013**

[193] Schedule 5, entry for Sumatriptan in the form Tablet 50 mg (as succinate)

insert in alphabetical order in the column headed "Brand": **Sumagraine Migraine Relief**

[194] Schedule 5, after entry for Tacrolimus in the form Capsule 0.5 mg

insert:

Tacrolimus	GRP-20892	Capsule 0.5 mg (once daily prolonged release)	Oral	ADVAGRAF XL Tacrolimus XR Sandoz

[195] Schedule 5, after entry for Tacrolimus in the form Capsule 1 mg

insert:

Tacrolimus	GRP-20891	Capsule 1 mg (once daily prolonged release)	Oral	ADVAGRAF XL Tacrolimus XR Sandoz
Tacrolimus	GRP-28602	Capsule 3 mg (once daily prolonged release)	Oral	ADVAGRAF XL Tacrolimus XR Sandoz

[196] Schedule 5, after entry for Tacrolimus in the form Capsule 5 mg

insert:

Tacrolimus	GRP-20887	Capsule 5 mg (once daily prolonged release)	Oral	ADVAGRAF XL Tacrolimus XR Sandoz

[197] Schedule 5, entry for Tadalafil

omit from the column headed "Schedule Equivalent Group": **GRP-24434** *substitute:* **GRP-24271**

[198] Schedule 5, entry for Tenofovir with emtricitabine in the form Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg

omit from the column headed "Brand": **Tenofovir Disoproxil Emtricitabine Mylan 300/200**

[199] Schedule 5, entry for Terbinafine

omit from the column headed "Schedule Equivalent Group": **GRP-20439** *substitute:* **GRP-20256**

[200] Schedule 5, entry for Teriparatide in the form Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen

insert in alphabetical order in the column headed "Brand": **Teriparatide Lupin**

[201] Schedule 5, entry for Topiramate in each of the forms: Tablet 100 mg; Tablet 200 mg; Tablet 25 mg; and Tablet 50 mg

omit from the column headed "Brand": **Topamax**

[202] Schedule 5, entry for Triamcinolone with neomycin, gramicidin and nystatin in the form Ear ointment containing triamcinolone acetonide 1 mg with neomycin 2.5 mg (as sulfate), gramicidin 250 micrograms and nystatin 100,000 units per g, 5 g

omit from the column headed "Schedule Equivalent Group": **GRP-19728** *substitute:* **GRP-19681**

[203] Schedule 5, entry for Trimethoprim

omit from the column headed "Brand": **Trimethoprim Mylan**

[204] Schedule 5, entry for Valproic acid in each of the forms: Tablet (enteric coated) containing sodium valproate 200 mg; and Tablet (enteric coated) containing sodium valproate 500 mg

insert in alphabetical order in the column headed "Brand": **APO-Sodium Valproate**

[205] Schedule 5, entry for Zoledronic acid in the form Solution for I.V. infusion 5 mg (as monohydrate) in 100 mL

omit from the column headed "Brand": **Osteova** *substitute:* **Osteovan**