PB 124 of 2024

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

National Health Act 1953

I, EDEN SIMON, Assistant Secretary (Acting), 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 28 November 2024

EDEN SIMON
Assistant Secretary (Acting)
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 (December Update) Instrument 2024*.

(2) This Instrument may also be cited as PB 124 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 December 2024*	*1 December 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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, after entry for Abemaciclib in the form Tablet 150 mg

insert:

Abiraterone	Tablet containing abiraterone acetate 250 mg	Oral	Abiraterone-Teva	TB	MP	C13945	120	2	120

[2] Schedule 1, Part 1, after entry for Abiraterone in the form Tablet containing abiraterone acetate 250 mg *[Brand: Zytiga]*

insert:

Abiraterone	Tablet containing abiraterone acetate 500 mg	Oral	Abiraterone-Teva	TB	MP	C13945	60	2	60

[3] Schedule 1, Part 1, entry for Ambrisentan in the form Tablet 5 mg *[Brand: Cipla Ambrisentan]*

omit from the column headed "Responsible Person": LR *substitute:* ZU

[4] Schedule 1, Part 1, entry for Ambrisentan in the form Tablet 10 mg *[Brand: Cipla Ambrisentan]*

omit from the column headed "Responsible Person": LR *substitute:* ZU

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

insert:

Atovaquone	Oral suspension 750 mg per 5 mL, 210 mL	Oral	ATOVACUE	JM	MP NP	C5609	1	0	1

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

insert:

Belzutifan	Tablet 40 mg	Oral	Welireg	MK	MP	C16180 C16208 C16215	90	5	90

[7] Schedule 1, Part 1, entries for Bortezomib in the form Powder for injection 3.5 mg

omit:

Bortezomib	Powder for injection 3.5 mg	Injection	BORTEZOMIB-TEVA	TB	MP	C11099 C13745		See Note 3	See Note 3	1	D(100)

[8] Schedule 1, Part 1, after entry for Cabazitaxel in the form Solution concentrate for I.V. infusion 60 mg in 6 mL *[Brand: Cabazitaxel Ever Pharma]*

insert:

Cabergoline	Tablet 500 micrograms	Oral	Dostamine	NB	MP	C5136 C5137 C5357 C5398	P5136 P5137 P5357 P5398	8	5	8	
Cabergoline	Tablet 500 micrograms	Oral	Dostamine	NB	MP	C14918 C14959 C14983 C15005	P14918 P14959 P14983 P15005	16	5	8	

[9] Schedule 1, Part 1, entries for Carbamazepine in the forms: Tablet 200 mg (controlled release); and Tablet 400 mg (controlled release)

substitute:

Carbamazepine	Tablet 200 mg (controlled release)	Oral	Tegretol CR 200	NV	PDP			200	0	100
Carbamazepine	Tablet 200 mg (controlled release)	Oral	Tegretol CR 200	NV	PDP			200	0	200
Carbamazepine	Tablet 200 mg (controlled release)	Oral	Tegretol CR 200	NV	MP NP			200	2	100
Carbamazepine	Tablet 200 mg (controlled release)	Oral	Tegretol CR 200	NV	MP NP			200	2	200
Carbamazepine	Tablet 200 mg (controlled release)	Oral	Tegretol CR 200	NV	MP NP		P14238	400	2	100
Carbamazepine	Tablet 200 mg (controlled release)	Oral	Tegretol CR 200	NV	MP NP		P14238	400	2	200
Carbamazepine	Tablet 400 mg (controlled release)	Oral	Tegretol CR 400	NV	PDP			200	0	100
Carbamazepine	Tablet 400 mg (controlled release)	Oral	Tegretol CR 400	NV	PDP			200	0	200
Carbamazepine	Tablet 400 mg (controlled release)	Oral	Tegretol CR 400	NV	MP NP			200	2	100

Carbamazepine	Tablet 400 mg (controlled release)	Oral	Tegretol CR 400	NV	MP NP			200	2	200
Carbamazepine	Tablet 400 mg (controlled release)	Oral	Tegretol CR 400	NV	MP NP		P14238	400	2	100
Carbamazepine	Tablet 400 mg (controlled release)	Oral	Tegretol CR 400	NV	MP NP		P14238	400	2	200

[10] Schedule 1, Part 1, omit entries for Carmellose in the form Eye drops containing carmellose sodium 5 mg per mL, 15 mL

[11] Schedule 1, Part 1, omit entries for Carmellose in the form Eye drops containing carmellose sodium 10 mg per mL, 15 mL

[12] Schedule 1, Part 1, omit entries for Carmellose with glycerin

[13] Schedule 1, Part 1, omit entries for Cefepime

[14] Schedule 1, Part 1, after entry for Clonazepam in the form Tablet 2 mg *[Maximum Quantity: 200; Number of Repeats: 2]*

insert:

Clonazepam	Tablet 2 mg (S19A)	Oral	Clonazepam USP (Advagen Pharma, USA)	LM	MP NP	C11746	P11746	100	3	100
Clonazepam	Tablet 2 mg (S19A)	Oral	Clonazepam USP (Advagen Pharma, USA)	LM	MP NP	C6296	P6296	200	2	100

[15] Schedule 1, Part 1, omit entries for Colestyramine in the form Sachet containing 4 g oral powder (s19A)

[16] Schedule 1, Part 1, entries for Cyproterone in the form Tablet containing cyproterone acetate 100 mg

omit:

Cyproterone	Tablet containing cyproterone acetate 100 mg	Oral	Pharmacor Cyproterone 100	CR	MP			50	5	50
Cyproterone	Tablet containing cyproterone acetate 100 mg	Oral	Pharmacor Cyproterone 100	CR	MP		P14238	100	5	50

[17] Schedule 1, Part 1, entry for Dapagliflozin *[Maximum Quantity: 28; Number of Repeats: 5]*

(a) insert in numerical order in the column headed "Circumstances": C16220

(b) insert in numerical order in the column headed "Purposes": P16220

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

(a) *insert in numerical order in the column headed "Circumstances":* C16164

(b) *insert in numerical order in the column headed "Purposes":* P16164

[19] **Schedule 1, Part 1, entry for Dapagliflozin with metformin in the form Tablet (modified release) containing 5 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride *[Maximum Quantity: 56; Number of Repeats: 5]***

(a) *insert in numerical order in the column headed "Circumstances":* C16158

(b) *insert in numerical order in the column headed "Purposes":* P16158

[20] **Schedule 1, Part 1, entry for Dapagliflozin with metformin in the form Tablet (modified release) containing 5 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride *[Maximum Quantity: 112; Number of Repeats: 5]***

(a) *insert in numerical order in the column headed "Circumstances":* C16162

(b) *insert in numerical order in the column headed "Purposes":* P16162

[21] **Schedule 1, Part 1, entry for Dapagliflozin with metformin in the form Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride *[Maximum Quantity: 28; Number of Repeats: 5]***

(a) *insert in numerical order in the column headed "Circumstances":* C16158

(b) *insert in numerical order in the column headed "Purposes":* P16158

[22] **Schedule 1, Part 1, entry for Dapagliflozin with metformin in the form Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride *[Maximum Quantity: 56; Number of Repeats: 5]***

(a) *insert in numerical order in the column headed "Circumstances":* C16162

(b) *insert in numerical order in the column headed "Purposes":* P16162

[23] **Schedule 1, Part 1, entry for Dapagliflozin with metformin in the form Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 500 mg metformin hydrochloride *[Maximum Quantity: 28; Number of Repeats: 5]***

(a) *insert in numerical order in the column headed "Circumstances":* C16158

(b) *insert in numerical order in the column headed "Purposes":* P16158

[24] **Schedule 1, Part 1, entry for Dapagliflozin with metformin in the form Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 500 mg metformin hydrochloride *[Maximum Quantity: 56; Number of Repeats: 5]***

(a) *insert in numerical order in the column headed "Circumstances":* C16162

(b) insert in numerical order in the column headed "Purposes": P16162

[25] Schedule 1, Part 1, after entry for Dasatinib in the form Tablet 20 mg *[Brand: Dasatinib Dr.Reddy's; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Dasatinib	Tablet 20 mg	Oral	Dasatinib Sandoz	SZ	MP	C9367 C9468 C9469 C9549	P9367 P9468 P9469 P9549	60	2	60
Dasatinib	Tablet 20 mg	Oral	Dasatinib Sandoz	SZ	MP	C12522 C12524 C12530 C12561 C12565 C12570	P12522 P12524 P12530 P12561 P12565 P12570	60	5	60

[26] Schedule 1, Part 1, after entry for Dasatinib in the form Tablet 50 mg *[Brand: Dasatinib Dr.Reddy's; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Dasatinib	Tablet 50 mg	Oral	Dasatinib Sandoz	SZ	MP	C9367 C9468 C9469 C9549	P9367 P9468 P9469 P9549	60	2	60
Dasatinib	Tablet 50 mg	Oral	Dasatinib Sandoz	SZ	MP	C12522 C12524 C12530 C12561 C12565 C12570	P12522 P12524 P12530 P12561 P12565 P12570	60	5	60

[27] Schedule 1, Part 1, after entry for Dasatinib in the form Tablet 70 mg *[Brand: Dasatinib Dr.Reddy's; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Dasatinib	Tablet 70 mg	Oral	Dasatinib Sandoz	SZ	MP	C9367 C9468 C9469 C9549	P9367 P9468 P9469 P9549	60	2	60
Dasatinib	Tablet 70 mg	Oral	Dasatinib Sandoz	SZ	MP	C12522 C12524 C12530 C12561 C12565 C12570	P12522 P12524 P12530 P12561 P12565 P12570	60	5	60

[28] Schedule 1, Part 1, after entry for Dasatinib in the form Tablet 100 mg *[Brand: Dasatinib Dr.Reddy's; Maximum Quantity: 30; Number of Repeats: 5]*

insert:

Dasatinib	Tablet 100 mg	Oral	Dasatinib Sandoz	SZ	MP	C9367 C9468 C9469 C9549	P9367 P9468 P9469 P9549	30	2	30

Dasatinib	Tablet 100 mg	Oral	Dasatinib Sandoz	SZ	MP	C12522 C12524 P12522 P12524 C12530 C12561 P12530 P12561 C12565 C12570 P12565 P12570	30	5	30

[29] Schedule 1, Part 1, entry for Daunorubicin with cytarabine

(a) omit from the column headed "Circumstances": See Note 3 *substitute:* C16187 C16197

(b) omit from the column headed "Purposes": See Note 3

[30] Schedule 1, Part 1, entries for Decitabine with cedazuridine

omit from the column headed "Responsible Person" (all instances): OS *substitute (all instances):* TJ

[31] 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:

Dienogest	Tablet 2 mg	Oral	Visanne	BN	MP NP	C16222	28	5	28

[32] Schedule 1, Part 1, entry for Dupilumab in the form Injection 300 mg in 2 mL single dose pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 5]*

omit from the column headed "Circumstances": C1250a7 *substitute:* C12507

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

insert:

Dutasteride with tamsulosin	Capsule containing dutasteride 500 micrograms with tamsulosin hydrochloride 400 micrograms	Oral	Dutasteride/Tamsulosin GQ Lupin 500/400		MP NP	C6189	P6189	30	5	30
Dutasteride with tamsulosin	Capsule containing dutasteride 500 micrograms with tamsulosin hydrochloride 400 micrograms	Oral	Dutasteride/Tamsulosin GQ Lupin 500/400		MP NP	C15004	P15004	60	5	30

[34] Schedule 1, Part 1, entries for Elotuzumab

substitute:

Elotuzumab	Powder for injection 300 mg	Injection	Empliciti	BQ	MP	C12847	See Note 3	See Note 3	1	D(100)
Elotuzumab	Powder for injection 400 mg	Injection	Empliciti	BQ	MP	C12847	See Note 3	See Note 3	1	D(100)

[35] Schedule 1, Part 1, omit entry for Epoprostenol in the form Powder for I.V. infusion 500 micrograms (as sodium) with 2 vials diluent 50 mL

[36] Schedule 1, Part 1, omit entry for Epoprostenol in the form Powder for I.V. infusion 1.5 mg (as sodium) with 2 vials diluent 50 mL

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

[38] Schedule 1, Part 1, after entry for Ezetimibe in the form Tablet 10 mg *[Brand: Zient 10mg; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Ezetimibe	Tablet 10 mg (S19A)	Oral	Ezetimibe USP (Camber, USA)	RQ	MP NP		30	5	90
Ezetimibe	Tablet 10 mg (S19A)	Oral	Ezetimibe USP (Camber, USA)	RQ	MP NP	P14238	60	5	90

[39] Schedule 1, Part 1, after entry for Gabapentin in the form Capsule 400 mg *[Brand: Nupentin 400]*

insert:

Gabapentin	Tablet 600 mg	Oral	APX-GABAPENTIN	TX	MP NP	C4928	100	5	100

[40] Schedule 1, Part 1, after entry for Ibuprofen in the form Tablet 400 mg *[Brand: Brufen; Maximum Quantity: 90; Number of Repeats: 3]*

insert:

Ibuprofen	Tablet 400 mg	Oral	WGR-IBUPROFEN 400	WG	MP NP MW PDP		30	0	30
Ibuprofen	Tablet 400 mg	Oral	WGR-IBUPROFEN 400	WG	PDP	P6256 P6282	90	0	30

Ibuprofen	Tablet 400 mg	Oral	WGR-IBUPROFEN 400	WG	MP NP	P6149 P6214 P6283	90	3		30

[41] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate)** ***[Brand: Imanib; Maximum Quantity: 60; Number of Repeats: 2]***

(a) *insert in numerical order in the column headed "Circumstances":* C9319

(b) *insert in numerical order in the column headed "Circumstances":* C13132

(c) *insert in numerical order in the column headed "Purposes":* P9319

(d) *insert in numerical order in the column headed "Purposes":* P13132

[42] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate)** ***[Brand: Imanib; Maximum Quantity: 60; Number of Repeats: 5]***

(a) *insert in numerical order in the column headed "Circumstances":* C9238

(b) *insert in numerical order in the column headed "Circumstances":* C9278

(c) *insert in numerical order in the column headed "Purposes":* P9238

(d) *insert in numerical order in the column headed "Purposes":* P9278

[43] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate)** ***[Brand: Imatinib Sandoz; Maximum Quantity: 60; Number of Repeats: 2]***

(a) *insert in numerical order in the column headed "Circumstances":* C9319

(b) *insert in numerical order in the column headed "Circumstances":* C13132

(c) *insert in numerical order in the column headed "Purposes":* P9319

(d) *insert in numerical order in the column headed "Purposes":* P13132

[44] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate)** ***[Brand: Imatinib Sandoz; Maximum Quantity: 60; Number of Repeats: 5]***

(a) *insert in numerical order in the column headed "Circumstances":* C9238

(b) *insert in numerical order in the column headed "Circumstances":* C9278

(c) *insert in numerical order in the column headed "Purposes":* P9238

(d) *insert in numerical order in the column headed "Purposes":* P9278

[45] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate) *[Brand: Imanib; Maximum Quantity: 30; Number of Repeats: 2]***

(a) *insert in numerical order in the column headed "Circumstances":* C9319

(b) *insert in numerical order in the column headed "Circumstances":* C13132

(c) *insert in numerical order in the column headed "Purposes":* P9319

(d) *insert in numerical order in the column headed "Purposes":* P13132

[46] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate) *[Brand: Imanib; Maximum Quantity: 30; Number of Repeats: 5]***

(a) *insert in numerical order in the column headed "Circumstances":* C9238

(b) *insert in numerical order in the column headed "Circumstances":* C9278

(c) *insert in numerical order in the column headed "Purposes":* P9238

(d) *insert in numerical order in the column headed "Purposes":* P9278

[47] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate) *[Brand: Imatinib Sandoz; Maximum Quantity: 30; Number of Repeats: 2]***

(a) *insert in numerical order in the column headed "Circumstances":* C9319

(b) *insert in numerical order in the column headed "Circumstances":* C13132

(c) *insert in numerical order in the column headed "Purposes":* P9319

(d) *insert in numerical order in the column headed "Purposes":* P13132

[48] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate) *[Brand: Imatinib Sandoz; Maximum Quantity: 30; Number of Repeats: 5]***

(a) *insert in numerical order in the column headed "Circumstances":* C9238

(b) *insert in numerical order in the column headed "Circumstances":* C9278

(c) *insert in numerical order in the column headed "Purposes":* P9238

(d) *insert in numerical order in the column headed "Purposes":* P9278

[49] **Schedule 1, Part 1, entries for Ketoprofen**

omit:

Ketoprofen	Capsule 200 mg (sustained release)	Oral	Oruvail SR	AV	PDP	C6214		28	0	28	
Ketoprofen	Capsule 200 mg (sustained release)	Oral	Oruvail SR	AV	MP NP	C6214		28	3	28	

[50] Schedule 1, Part 1, entries for Lenalidomide in the form Capsule 5 mg

omit:

Lenalidomide	Capsule 5 mg	Oral	Cipla Lenalidomide	LR	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
Lenalidomide	Capsule 5 mg	Oral	Cipla Lenalidomide	LR	MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
Lenalidomide	Capsule 5 mg	Oral	Cipla Lenalidomide	LR	MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)

[51] Schedule 1, Part 1, entries for Lenalidomide in the form Capsule 10 mg

omit:

Lenalidomide	Capsule 10 mg	Oral	Cipla Lenalidomide	LR	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
Lenalidomide	Capsule 10 mg	Oral	Cipla Lenalidomide	LR	MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
Lenalidomide	Capsule 10 mg	Oral	Cipla Lenalidomide	LR	MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)

[52] Schedule 1, Part 1, entries for Lenalidomide in the form Capsule 15 mg

omit:

Lenalidomide	Capsule 15 mg	Oral	Cipla Lenalidomide	LR	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
Lenalidomide	Capsule 15 mg	Oral	Cipla Lenalidomide	LR	MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
Lenalidomide	Capsule 15 mg	Oral	Cipla Lenalidomide	LR	MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)

[53] Schedule 1, Part 1, entries for Lenalidomide in the form Capsule 25 mg

omit:

Lenalidomide	Capsule 25 mg	Oral	Cipla Lenalidomide	LR	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
Lenalidomide	Capsule 25 mg	Oral	Cipla Lenalidomide	LR	MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)

[54] Schedule 1, Part 1, entries for Lisdexamfetamine

omit from the column headed "Circumstances" (all instances): C10792 *substitute (all instances):* C16154

[55] Schedule 1, Part 1, omit entry for Medroxyprogesterone in the form Injection containing medroxyprogesterone acetate 150 mg in 1 mL

[56] Schedule 1, Part 1, after entry for Metformin in the form Tablet containing metformin hydrochloride 500 mg *[Brand: Diaformin; Maximum Quantity: 200; Number of Repeats: 5]*

insert:

Metformin	Tablet containing metformin hydrochloride 500 mg	Oral	Diaformin Viatris	MQ	MP NP		100	5		100
Metformin	Tablet containing metformin hydrochloride 500 mg	Oral	Diaformin Viatris	MQ	MP NP	P14238	200	5		100

[57] Schedule 1, Part 1, after entry for Metformin in the form Tablet containing metformin hydrochloride 1 g *[Brand: Metformin Sandoz; Maximum Quantity: 180; Number of Repeats: 5]*

insert:

Metformin	Tablet containing metformin hydrochloride 1 g	Oral	METFORMIN-WGR	WG	MP NP		90	5		90
Metformin	Tablet containing metformin hydrochloride 1 g	Oral	METFORMIN-WGR	WG	MP NP	P14238	180	5		90

[58] Schedule 1, Part 1, after entry for Methadone in the form Oral liquid containing methadone hydrochloride 25 mg per 5 mL in 200 mL bottle, 1 mL *[Brand: Biodone Forte]*

insert:

Methadone	Tablet containing methadone hydrochloride 10 mg	Oral	METHADONE-AFT	AE	MP NP	C15994 C15996 C16000	P15994 P15996 P16000	20	0	V15994 V15996 V16000	20
Methadone	Tablet containing methadone hydrochloride	Oral	METHADONE-AFT	AE	MP NP	C11696	P11696	120	0	V11696	20

	10 mg										

[59] Schedule 1, Part 1, entries for Methylphenidate in each of the forms: Capsule containing methylphenidate hydrochloride 10 mg (modified release); Capsule containing methylphenidate hydrochloride 20 mg (modified release); Capsule containing methylphenidate hydrochloride 30 mg (modified release); Capsule containing methylphenidate hydrochloride 40 mg (modified release); and Capsule containing methylphenidate hydrochloride 60 mg (modified release)

omit from the column headed "Circumstances" (all instances): C13922 *substitute (all instances):* C16152

[60] Schedule 1, Part 1, entries for Methylphenidate in each of the forms: Tablet containing methylphenidate hydrochloride 18 mg (extended release); Tablet containing methylphenidate hydrochloride 27 mg (extended release); Tablet containing methylphenidate hydrochloride 36 mg (extended release); and Tablet containing methylphenidate hydrochloride 54 mg (extended release)

omit from the column headed "Circumstances" (all instances): C10717 *substitute (all instances):* C16189

[61] Schedule 1, Part 1, entry for Molnupiravir

omit from the column headed "Circumstances": C15050 C15055 C15056 C15062 *substitute:* C16190 C16191 C16200 C16201

[62] Schedule 1, Part 1, entries for Nevirapine in the form Tablet 200 mg

omit:

Nevirapine	Tablet 200 mg	Oral	Nevirapine Alphapharm	AF	MP NP	C4454 C4512	120	5	60	D(100)

[63] Schedule 1, Part 1, entry for Nirmatrelvir and ritonavir

omit from the column headed "Circumstances": C13748 C13759 C13821 C15049 *substitute:* C16155 C16156 C16192 C16223

[64] Schedule 1, Part 1, entries for Nivolumab with relatlimab

substitute:

Nivolumab with relatlimab	Solution concentrate for I.V. infusion containing 240 mg nivolumab and 80 mg relatlimab in 20 mL	Injection	Opdualag	BQ	MP	C16151 C16188	See Note 3	See Note 3	1	D(100)

[65] Schedule 1, Part 1, after entry for Olmesartan with amlodipine in the form Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate) *[Brand: Sevikar 20/5; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Olmesartan with amlodipine	Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate)	Oral	APO-OLMESARTAN/AMLODIPINE 40/10	TY	MP NP	C4373	P4373	30	5	30
Olmesartan with amlodipine	Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate)	Oral	APO-OLMESARTAN/AMLODIPINE 40/10	TY	MP NP	C14839	P14839	60	5	30

[66] Schedule 1, Part 1, entries for Paraffin in the form Pack containing 2 tubes eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g

omit:

Paraffin	Pack containing 2 tubes eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g	Application to the eye	Refresh Night Time	VE	MP NP AO			1	5	1
Paraffin	Pack containing 2 tubes eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g	Application to the eye	Refresh Night Time	VE	MP NP AO		P14238	2	5	1

[67] Schedule 1, Part 1, after entry for Pioglitazone in the form Tablet 45 mg (as hydrochloride) *[Brand: APOTEX-Pioglitazone; Maximum Quantity: 56; Number of Repeats: 5]*

insert:

Pioglitazone	Tablet 45 mg (as hydrochloride)	Oral	ARX-PIOGLITAZONE	XT	MP NP	C15321	P15321	28	5	28
Pioglitazone	Tablet 45 mg (as hydrochloride)	Oral	ARX-PIOGLITAZONE	XT	MP NP	C15290	P15290	56	5	28

[68] Schedule 1, Part 1, omit entry for Prochlorperazine in the form Tablet containing prochlorperazine maleate 5 mg (S19A)

[69] Schedule 1, Part 1, after entry for Rivaroxaban in the form Tablet 2.5 mg *[Brand: Rivaroxaban-Teva; Maximum Quantity: 120; Number of Repeats: 5]*

insert:

Rivaroxaban	Tablet 2.5 mg	Oral	RIVOXA	CR	MP NP	C10992	P10992	60	5	60

Rivaroxaban	Tablet 2.5 mg	Oral	RIVOXA	CR	MP	C11013	P11013	60	5	60
Rivaroxaban	Tablet 2.5 mg	Oral	RIVOXA	CR	MP NP	C14298	P14298	120	5	60

[70] Schedule 1, Part 1, after entry for Rivaroxaban in the form Tablet 10 mg *[Brand: iXarola; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Rivaroxaban	Tablet 10 mg	Oral	Rivaroxaban Sandoz	SZ	MP NP	C4402	P4402	30	0	30
Rivaroxaban	Tablet 10 mg	Oral	Rivaroxaban Sandoz	SZ	MP NP	C4132	P4132	30	5	30
Rivaroxaban	Tablet 10 mg	Oral	Rivaroxaban Sandoz	SZ	MP NP	C14300	P14300	60	5	30

[71] Schedule 1, Part 1, after entry for Rivaroxaban in the form Tablet 10 mg *[Brand: Rivaroxaban-Teva; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Rivaroxaban	Tablet 10 mg	Oral	Rivoxa	CR	MP NP	C4402	P4402	30	0	30
Rivaroxaban	Tablet 10 mg	Oral	Rivoxa	CR	MP NP	C4132	P4132	30	5	30
Rivaroxaban	Tablet 10 mg	Oral	Rivoxa	CR	MP NP	C14300	P14300	60	5	30

[72] Schedule 1, Part 1, after entry for Rivaroxaban in the form Tablet 15 mg *[Brand: iXarola; Maximum Quantity: 56; Number of Repeats: 5]*

insert:

Rivaroxaban	Tablet 15 mg	Oral	Rivaroxaban Sandoz	SZ	MP NP	C4269	P4269	28	5	28
Rivaroxaban	Tablet 15 mg	Oral	Rivaroxaban Sandoz	SZ	MP NP	C4098 C5098	P4098 P5098	42	0	42
Rivaroxaban	Tablet 15 mg	Oral	Rivaroxaban Sandoz	SZ	MP NP	C14301	P14301	56	5	28

[73] **Schedule 1, Part 1, after entry for Rivaroxaban in the form Tablet 15 mg *[Brand: Rivaroxaban-Teva; Maximum Quantity: 56; Number of Repeats: 5]***

insert:

Rivaroxaban	Tablet 15 mg	Oral	Rivoxa	CR	MP NP	C4269	P4269	28	5	28
Rivaroxaban	Tablet 15 mg	Oral	Rivoxa	CR	MP NP	C4098 C5098	P4098 P5098	42	0	42
Rivaroxaban	Tablet 15 mg	Oral	Rivoxa	CR	MP NP	C14301	P14301	56	5	28

[74] **Schedule 1, Part 1, after entry for Rivaroxaban in the form Tablet 20 mg *[Brand: iXarola; Maximum Quantity: 56; Number of Repeats: 5]***

insert:

Rivaroxaban	Tablet 20 mg	Oral	Rivaroxaban Sandoz	SZ	MP NP	C4099 C4132 C4268 C4269	P4099 P4132 P4268 P4269	28	5	28
Rivaroxaban	Tablet 20 mg	Oral	Rivaroxaban Sandoz	SZ	MP NP	C14264 C14300 C14301 C14318	P14264 P14300 P14301 P14318	56	5	28

[75] **Schedule 1, Part 1, after entry for Rivaroxaban in the form Tablet 20 mg *[Brand: Rivaroxaban-Teva; Maximum Quantity: 56; Number of Repeats: 5]***

insert:

Rivaroxaban	Tablet 20 mg	Oral	Rivoxa	CR	MP NP	C4099 C4132 C4268 C4269	P4099 P4132 P4268 P4269	28	5	28
Rivaroxaban	Tablet 20 mg	Oral	Rivoxa	CR	MP NP	C14264 C14300 C14301 C14318	P14264 P14300 P14301 P14318	56	5	28

[76] **Schedule 1, Part 1, after entry for Rivastigmine in the form Transdermal patch 27 mg *[Authorised Prescriber MP; Maximum Quantity: 30; Number of Repeats: 5]***

insert:

Rizatriptan	Tablet (orally disintegrating) 10 mg (as benzoate)	Oral	APO-RIZATRIPTAN ODT	TW	MP NP	C5708		4	5	2

[77] **Schedule 1, Part 1, entry for Testosterone in the form Transdermal cream 50 mg per mL, 50 mL *[Maximum Quantity: 1; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* C11838 C11891 C11947 C11962 C11963 *substitute:* C16166 C16194 C16204 C16211 C16212

(b) *omit from the column headed "Purposes":* P11838 P11891 P11947 P11962 P11963 *substitute:* P16166 P16194 P16204 P16211 P16212

[78] **Schedule 1, Part 1, entry for Testosterone in the form Transdermal cream 50 mg per mL, 50 mL *[Maximum Quantity: 2; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* C15622 C15623 C15654 C15739 C15756 *substitute:* C16186 C16195 C16206 C16207 C16214

(b) *omit from the column headed "Purposes":* P15622 P15623 P15654 P15739 P15756 *substitute:* P16186 P16195 P16206 P16207 P16214

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

(a) *omit from the column headed "Circumstances":* C14696

(b) *omit from the column headed "Purposes":* P14696

[80] **Schedule 1, Part 1, entry for Upadacitinib in the form Tablet 30 mg *[Maximum Quantity: 28; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* C14696

(b) *omit from the column headed "Purposes":* P14696

[81] **Schedule 1, Part 1, entry for Upadacitinib in the form Tablet 45 mg *[Maximum Quantity: 28; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C14696

(b) *omit from the column headed "Purposes":* P14696

[82] **Schedule 1, Part 1, entries for Vancomycin**

omit:

Vancomycin	Powder for injection 500 mg (500,000 I.U.) (as hydrochloride)	Injection	Vancomycin Alphapharm	AF	MP	C5717	P5717	2	0	1
Vancomycin	Powder for injection 500 mg (500,000 I.U.) (as hydrochloride)	Injection	Vancomycin Alphapharm	AF	PDP	C5801	P5801	2	0	1
Vancomycin	Powder for injection 500 mg (500,000 I.U.) (as hydrochloride)	Injection	Vancomycin Alphapharm	AF	MP	C5716 C5769	P5716 P5769	5	0	1

Vancomycin	Powder for injection 1 g (1,000,000 I.U.) (as hydrochloride)	Injection	Vancomycin Alphapharm	AF	MP	C5717	P5717	1	0	1
Vancomycin	Powder for injection 1 g (1,000,000 I.U.) (as hydrochloride)	Injection	Vancomycin Alphapharm	AF	PDP	C5801	P5801	1	0	1
Vancomycin	Powder for injection 1 g (1,000,000 I.U.) (as hydrochloride)	Injection	Vancomycin Alphapharm	AF	MP	C5716 C5769	P5716 P5769	3	0	1

[83] Schedule 1, Part 1, after entry for Vancomycin in the form Capsule 250 mg (250,000 I.U.) (as hydrochloride) *[Brand: Vancomycin BNM 250mg]*

insert:

Vancomycin	Powder for injection 500 mg (500,000 I.U.) (as hydrochloride)	Injection	Vancomycin Viatris	AL	MP	C5717	P5717	2	0	1
Vancomycin	Powder for injection 500 mg (500,000 I.U.) (as hydrochloride)	Injection	Vancomycin Viatris	AL	PDP	C5801	P5801	2	0	1
Vancomycin	Powder for injection 500 mg (500,000 I.U.) (as hydrochloride)	Injection	Vancomycin Viatris	AL	MP	C5716 C5769	P5716 P5769	5	0	1
Vancomycin	Powder for injection 1 g (1,000,000 I.U.) (as hydrochloride)	Injection	Vancomycin Viatris	AL	MP	C5717	P5717	1	0	1
Vancomycin	Powder for injection 1 g (1,000,000 I.U.) (as hydrochloride)	Injection	Vancomycin Viatris	AL	PDP	C5801	P5801	1	0	1
Vancomycin	Powder for injection 1 g (1,000,000 I.U.) (as hydrochloride)	Injection	Vancomycin Viatris	AL	MP	C5716 C5769	P5716 P5769	3	0	1

[84] Schedule 1, Part 1, entries for Varenicline

substitute:

Varenicline	Box containing 11 tablets 0.5 mg and 42 tablets 1 mg	Oral	Champix	PF	MP NP	C6871		1	0	1

Varenicline	Box containing 11 tablets 0.5 mg and 42 tablets 1 mg	Oral	PHARMACOR VARENICLINE	CR	MP NP	C6871		1	0	1	
Varenicline	Box containing 11 tablets 0.5 mg and 42 tablets 1 mg	Oral	VARENAPIX	TX	MP NP	C6871		1	0	1	
Varenicline	Box containing 11 tablets 0.5 mg and 42 tablets 1 mg	Oral	Varenicline Sandoz	SZ	MP NP	C6871		1	0	1	
Varenicline	Box containing 11 tablets 0.5 mg and 42 tablets 1 mg	Oral	Varenicline Viatris	AF	MP NP	C6871		1	0	1	
Varenicline	Tablet 1 mg	Oral	Champix	PF	MP NP	C6885	P6885	56	2	56	
Varenicline	Tablet 1 mg	Oral	Champix	PF	MP NP	C7483	P7483	112	0	56	
Varenicline	Tablet 1 mg	Oral	PHARMACOR VARENICLINE	CR	MP NP	C6885	P6885	56	2	56	
Varenicline	Tablet 1 mg	Oral	PHARMACOR VARENICLINE	CR	MP NP	C7483	P7483	112	0	56	
Varenicline	Tablet 1 mg	Oral	VARENAPIX	TX	MP NP	C6885	P6885	56	2	56	
Varenicline	Tablet 1 mg	Oral	VARENAPIX	TX	MP NP	C7483	P7483	112	0	56	
Varenicline	Tablet 1 mg	Oral	Varenicline Sandoz	SZ	MP NP	C6885	P6885	56	2	56	
Varenicline	Tablet 1 mg	Oral	Varenicline Sandoz	SZ	MP NP	C7483	P7483	112	0	56	
Varenicline	Tablet 1 mg	Oral	Varenicline Viatris	AF	MP NP	C6885	P6885	56	2	56	
Varenicline	Tablet 1 mg	Oral	Varenicline Viatris	AF	MP NP	C7483	P7483	112	0	56	

[85] Schedule 1, Part 1, entry for Zoledronic acid in the form Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL *[Brand: Zoledronate-DRLA 4]*

substitute:

Zoledronic acid	Injection concentrate for I.V. infusion 4 mg (as	Injection	Zoledronate-DRLA 4	RZ	MP	C14729 C14735	P14729 P14735	1	0	1	PB(100)	

	monohydrate) in 5 mL									
Zoledronic acid	Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL	Injection	Zoledronate-DRLA 4	RZ	MP	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328	P5605 P5703 P5704 P5735 P9268 P9304 P9317 P9328	1	11	1	PB(100)

[86] Schedule 1, Part 2, after entry for Budesonide with formoterol

insert:

Carmellose	Eye drops containing carmellose sodium 5 mg per mL, 15 mL	Application to the eye	Refresh Tears Plus	VE	1	
Carmellose	Eye drops containing carmellose sodium 10 mg per mL, 15 mL	Application to the eye	Refresh Liquigel	VE	1	
Carmellose with glycerin	Eye drops containing carmellose sodium 5 mg with glycerin 9 mg per mL, 15 mL	Application to the eye	Optive	VE	1	
Evolocumab	Injection 420 mg in 3.5 mL single use pre-filled cartridge	Injection	Repatha	AN	1	

[87] Schedule 3, after entry for Responsible Person JC

insert:

JM	Glenmark Pharmaceuticals (Australia) Pty Ltd	23 116 922 500

[88] Schedule 3, after entry for Responsible Person TG

insert:

TJ	Taiho Pharma Oceania Pty Ltd	97 675 212 530

[89] Schedule 3, after entry for Responsible Person ZS

insert:

ZU	Seekwell Pty Ltd	91 624 401 618

[90] Schedule 4, Part 1, omit entry for Circumstances Code "C10717"

[91] Schedule 4, Part 1, omit entry for Circumstances Code "C10792"

[92] Schedule 4, Part 1, omit entry for Circumstances Code "C11838"

[93] **Schedule 4, Part 1, omit entry for Circumstances Code "C11891"**

[94] **Schedule 4, Part 1, omit entry for Circumstances Code "C11947"**

[95] **Schedule 4, Part 1, omit entry for Circumstances Code "C11962"**

[96] **Schedule 4, Part 1, omit entry for Circumstances Code "C11963"**

[97] **Schedule 4, Part 1, omit entry for Circumstances Code "C12891"**

[98] **Schedule 4, Part 1, omit entry for Circumstances Code "C13748"**

[99] **Schedule 4, Part 1, omit entry for Circumstances Code "C13759"**

[100] **Schedule 4, Part 1, omit entry for Circumstances Code "C13821"**

[101] **Schedule 4, Part 1, omit entry for Circumstances Code "C13922"**

[102] **Schedule 4, Part 1, omit entry for Circumstances Code "C14696"**

[103] **Schedule 4, Part 1, omit entry for Circumstances Code "C14812"**

[104] **Schedule 4, Part 1, omit entry for Circumstances Code "C14815"**

[105] **Schedule 4, Part 1, omit entry for Circumstances Code "C14819"**

[106] **Schedule 4, Part 1, omit entry for Circumstances Code "C14829"**

[107] **Schedule 4, Part 1, omit entry for Circumstances Code "C15049"**

[108] **Schedule 4, Part 1, omit entry for Circumstances Code "C15050"**

[109] **Schedule 4, Part 1, omit entry for Circumstances Code "C15055"**

[110] **Schedule 4, Part 1, omit entry for Circumstances Code "C15056"**

[111] **Schedule 4, Part 1, omit entry for Circumstances Code "C15062"**

[112] **Schedule 4, Part 1, entry for Circumstances Code "C15303"**

omit entry for Circumstances Code "C15303" and substitute:

C15303	P15303	CN15303	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 m^2; 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. 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

[113] Schedule 4, Part 1, entry for Circumstances Code "C15456"

omit entry for Circumstances Code "C15456" and substitute:

C15456	P15456	CN15456	Midazolam	Generalized convulsive status epilepticus Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures

[114] Schedule 4, Part 1, entry for Circumstances Code "C15457"

omit entry for Circumstances Code "C15457" and substitute:

C15457	P15457	CN15457	Midazolam	Generalized convulsive status epilepticus Initial treatment Patient must have been assessed to be at significant risk of status epilepticus; AND	Compliance with Authority Required procedures

				Patient must have experienced at least one prolonged seizure (greater than 5 minutes duration) requiring emergency medical attention within the previous 5 years. Patient must be at least one year of age. The treatment must initiated by a specialist physician experienced in the treatment of epilepsy.	

[115] Schedule 4, Part 1, entry for Circumstances Code "C15560"

(a) omit from the column headed "Listed Drug": Carmellose

(b) omit from the column headed "Listed Drug": Carmellose with glycerin

[116] Schedule 4, Part 1, omit entry for Circumstances Code "C15622"

[117] Schedule 4, Part 1, omit entry for Circumstances Code "C15623"

[118] Schedule 4, Part 1, entry for Circumstances Code "C15640"

(a) omit from the column headed "Listed Drug": Carmellose

(b) omit from the column headed "Listed Drug": Carmellose with glycerin

[119] Schedule 4, Part 1, omit entry for Circumstances Code "C15654"

[120] Schedule 4, Part 1, omit entry for Circumstances Code "C15739"

[121] Schedule 4, Part 1, omit entry for Circumstances Code "C15756"

[122] Schedule 4, Part 1, entry for Circumstances Code "C15818"

omit entry for Circumstances Code "C15818" and substitute:

C15818	P15818	CN15818	Trastuzumab emtansine	Early HER2 positive breast cancer Initial adjuvant treatment The treatment must be prescribed within 12 weeks after surgery; AND Patient must have, prior to commencing treatment with this drug, evidence of residual invasive cancer in the breast and/or axillary lymph nodes following completion of surgery, as demonstrated by a pathology report; AND Patient must have completed systemic neoadjuvant therapy that included trastuzumab and taxane-based chemotherapy prior to surgery; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND	Compliance with Written Authority Required procedures

				The treatment must not extend beyond 42 weeks (14 cycles) duration under the initial and the continuing treatment restrictions combined. Authority applications for initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (a) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating evidence of residual invasive carcinoma in the breast and/or axillary lymph nodes following completion of surgery. The pathology report must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; and (ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	

[123] Schedule 4, Part 1, entry for Circumstances Code "C15819"

omit entry for Circumstances Code "C15819" and substitute:

C15819	P15819	CN15819	Trastuzumab emtansine	Early HER2 positive breast cancer Continuing adjuvant 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 not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND The treatment must not extend beyond 42 weeks (14 cycles) duration under the initial and the continuing treatment restrictions combined.	Compliance with Authority Required procedures

[124] Schedule 4, Part 1, entry for Circumstances Code "C15820"

omit entry for Circumstances Code "C15820" and substitute:

C15820	P15820	CN15820	Trastuzumab	Early HER2 positive breast cancer Initial treatment (3 weekly regimen) Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant); AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND	Compliance with Authority Required procedures - Streamlined Authority Code 15820

				Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance. HER2 positivity must be demonstrated by in situ hybridisation (ISH). Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.	

[125] Schedule 4, Part 1, entry for Circumstances Code "C15826"

omit entry for Circumstances Code "C15826" and substitute:

C15826	P15826	CN15826	Trastuzumab deruxtecan	Metastatic (Stage IV) HER2 positive breast cancer Patient must have evidence of human epidermal growth factor (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) in either the primary tumour/a metastatic lesion - establish this finding once only with the first PBS prescription; AND The condition must have progressed following treatment with at least one prior HER2 directed regimen for metastatic breast cancer; OR The condition must have, at the time of treatment initiation with this drug, progressed during/within 6 months following adjuvant treatment with a HER2 directed therapy; AND Patient must have, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND The treatment must not be prescribed where any of the following is present: (i) left ventricular ejection fraction of less than 50%, (ii) symptomatic heart failure; confirm cardiac function testing for the first PBS prescription only. Patient must be undergoing initial treatment with this drug - the following are true: (i) this is the first prescription for this drug, (ii) this prescription seeks no more than 3 repeat prescriptions; OR Patient must be undergoing continuing treatment with drug - the following are true: (i) there has been an absence of further disease progression whilst on active treatment with this drug, (ii) this prescription does not seek to re-treat after disease progression, (iii) this prescription seeks no more than 8 repeat prescriptions. Confirm that the following information is documented/retained in the patient's medical records once only with the first PBS prescription: 1) Evidence of HER2 gene amplification (evidence obtained in relation to past PBS treatment is acceptable).	Compliance with Authority Required procedures

				2) Details of prior HER2 directed drug regimens prescribed for the patient. 3) Cardiac function test results (evidence obtained in relation to past PBS treatment is acceptable).	

[126] Schedule 4, Part 1, entry for Circumstances Code "C15827"

omit entry for Circumstances Code "C15827" and substitute:

C15827	P15827	CN15827	Trastuzumab emtansine	Metastatic (Stage IV) HER2 positive breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for metastatic (Stage IV) HER2 positive breast cancer; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. The treatment must not exceed a lifetime total of one continuous course for this PBS indication.	Compliance with Authority Required procedures

[127] Schedule 4, Part 1, entry for Circumstances Code "C15828"

omit entry for Circumstances Code "C15828" and substitute:

C15828	P15828	CN15828	Trastuzumab emtansine	Metastatic (Stage IV) HER2 positive breast cancer Initial treatment Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, confirmed through a pathology report from an Approved Pathology Authority; AND The condition must have progressed following treatment with pertuzumab and trastuzumab in combination; OR The condition must have progressed during or within 6 months of completing adjuvant therapy with trastuzumab; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.	Compliance with Authority Required procedures

				The following information must be provided by the prescriber at the time of application: (a) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH). (b) dates of treatment with trastuzumab and pertuzumab; (c) date of demonstration of progression following treatment with trastuzumab and pertuzumab; or (d) date of demonstration of progression and date of completion of adjuvant trastuzumab treatment. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. All reports must be documented in the patient's medical records. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval.	

[128] Schedule 4, Part 1, entry for Circumstances Code "C15831"

omit entry for Circumstances Code "C15831" and substitute:

C15831	P15831	CN15831	Trastuzumab	Early HER2 positive breast cancer Initial treatment (weekly regimen) Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant); AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance. HER2 positivity must be demonstrated by in situ hybridisation (ISH). Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 15831

[129] Schedule 4, Part 1, entry for Circumstances Code "C15832"

omit entry for Circumstances Code "C15832" and substitute:

C15832	P15832	CN15832	Trastuzumab deruxtecan	Unresectable and/or metastatic HER2-low breast cancer Patient must have evidence of human epidermal growth factor receptor 2 (HER2)-low disease; AND Patient must have received prior chemotherapy in the metastatic setting; OR Patient must have developed disease recurrence during or within 6 months of completing adjuvant chemotherapy; AND Patient must have received or be ineligible for endocrine therapy in the metastatic setting, if hormone receptor positive; AND Patient must have, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND The treatment must not be prescribed where any of the following is present: (i) left ventricular ejection fraction of less than 50%, (ii) symptomatic heart failure; confirm cardiac function testing for the first PBS prescription only. Patient must be undergoing initial treatment with this drug - the following are true: (i) this is the first prescription for this drug, (ii) this prescription seeks no more than 3 repeat prescriptions; OR Patient must be undergoing continuing treatment with drug - the following are true: (i) there has been an absence of further disease progression whilst on active treatment with this drug, (ii) this prescription does not seek to re-treat after disease progression, (iii) this prescription seeks no more than 8 repeat prescriptions. HER2-low is defined as an immunohistochemical (IHC) score of 1+ or an IHC score of 2+ and a negative result on in situ hybridization (ISH). Confirm that the following information is documented/retained in the patient's medical records once only with the first PBS prescription: 1) Evidence of HER2-low status 2) Details of prior drug regimens prescribed for the patient 3) Cardiac function test results	Compliance with Authority Required procedures

[130] Schedule 4, Part 1, omit entry for Circumstances Code "C16067"

[131] Schedule 4, Part 1, after entry for Circumstances Code "C16148"

insert:

C16151	P16151	CN16151	Nivolumab with relatlimab	Unresectable Stage III or Stage IV malignant melanoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority Code 16151

				The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen. The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information. The prescription must include the amount of nivolumab with relatlimab (Opdualag) that is appropriate to be prescribed for the patient. For the purposes of PBS subsidy, the maximum amount requested is based on the nivolumab dose only. The prescribed amount of nivolumab must be expressed in milligrams.	
C16152	P16152	CN16152	Methylphenidate	Attention deficit hyperactivity disorder Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events; AND Patient must require continuous coverage over 8 hours; AND The treatment must not exceed a maximum daily dose of 80 mg of PBS-subsidised treatment with this drug. Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive; OR Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; OR Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age. A retrospective diagnosis of ADHD for the purposes of administering this restriction is: (i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and (ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party, has occurred and which supports point (i) above.	Compliance with Authority Required procedures
C16154	P16154	CN16154	Lisdexamfetamine	Attention deficit hyperactivity disorder Patient must require continuous coverage over 12 hours; AND The treatment must not exceed a maximum daily dose of 70 mg of PBS-subsidised treatment with this drug. Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive; OR	Compliance with Authority Required procedures

				Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; OR Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age. A retrospective diagnosis of ADHD for the purposes of administering this restriction is: (i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and (ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party, has occurred and which supports point (i) above.	
C16155	P16155	CN16155	Nirmatrelvir and ritonavir	SARS-CoV-2 infection Patient must have received a positive nucleic acid test result; OR Patient must have received a positive rapid antigen test (RAT) result; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND The treatment must be initiated within 5 days of symptom onset; OR The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic. Patient must be at least 70 years of age. Access to this drug through this restriction is permitted irrespective of vaccination status. Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record. Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record. This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.	Compliance with Authority Required procedures - Streamlined Authority Code 16155
C16156	P16156	CN16156	Nirmatrelvir and ritonavir	SARS-CoV-2 infection Patient must have received a positive nucleic acid test result; OR Patient must have received a positive rapid antigen test (RAT) result; AND Patient must have at least one sign or symptom attributable to COVID-19; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND The treatment must be initiated within 5 days of symptom onset.	Compliance with Authority Required procedures - Streamlined Authority Code 16156

				Patient must be both: (i) at least 50 years of age, (ii) at high risk. For the purpose of administering this restriction, high risk is defined as either a past COVID-19 infection episode resulting in hospitalisation, or the presence of at least two of the following conditions: 1. The patient is in residential aged care, 2. The patient has disability with multiple comorbidities and/or frailty, 3. Neurological conditions, including stroke and dementia and demyelinating conditions, 4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease, 5. Heart failure, coronary artery disease, cardiomyopathies, 6. Obesity (BMI greater than 30 kg/m ^{2}), 7. Diabetes type I or II, requiring medication for glycaemic control, 8. Renal impairment (eGFR less than 60mL/min), 9. Cirrhosis, or 10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above. Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records. For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell. Access to this drug through this restriction is permitted irrespective of vaccination status. Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record. Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record. This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.	
C16158	P16158	CN16158	Dapagliflozin with metformin	Diabetes mellitus type 2 Patient must have cardiovascular disease; OR Patient must be at high risk of a cardiovascular event; OR Patient must identify as Aboriginal or Torres Strait Islander.	Compliance with Authority Required procedures - Streamlined Authority Code 16158

				Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.	
C16162	P16162	CN16162	Dapagliflozin with metformin	Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have cardiovascular disease; OR Patient must be at high risk of a cardiovascular event; OR Patient must identify as Aboriginal or Torres Strait Islander. Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 16162
C16164	P16164	CN16164	Dapagliflozin	Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; unless contraindicated/intolerant; AND Patient must have cardiovascular disease; OR Patient must be at high risk of a cardiovascular event; OR Patient must identify as Aboriginal or Torres Strait Islander. Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 16164
C16166	P16166	CN16166	Testosterone	Androgen deficiency Patient must have an established pituitary or testicular disorder. Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The treatment must be applied to the scrotum, where possible. The name of the specialist must be included in the authority application.	Compliance with Authority Required procedures
C16180	P16180	CN16180	Belzutifan	Von Hippel-Lindau (VHL) disease Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same tumour type; AND Patient must not have developed VHL-associated metastatic disease; AND Patient must have demonstrated clinical improvement or stabilisation of the condition while being treated with this drug, the details of which must be kept with the patient's record; AND	Compliance with Authority Required procedures

				The treatment must be the sole PBS-subsidised therapy for VHL disease associated tumours. Must be treated by a physician with expertise in the management of VHL disease associated tumours. Patients who cease therapy for reasons other than, clinical disease progression or metastasis, may re-initiate PBS-subsidised treatment through the initiating or recommencing treatment phase. For the purpose of administering this restriction, clinical improvement or stabilisation of the patient's condition includes but is not limited to: (i) avoidance of surgery; (ii) avoidance of renal replacement therapy such as dialysis or renal transplantation in patients with VHL- associated renal cell carcinoma (RCC); (iii) experiencing clinical benefit in at least one of the VHL associated conditions, as determined by the treating clinician(s).	
C16186	P16186	CN16186	Testosterone	Androgen deficiency The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have an established pituitary or testicular disorder. Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The treatment must be applied to the scrotum, where possible. The name of the specialist must be included in the authority application.	Compliance with Authority Required procedures
C16187	P16187	CN16187	Daunorubicin with cytarabine	Acute Myeloid Leukaemia Induction therapy Patient must not have received prior chemotherapy as induction therapy for this condition; AND The condition must be either: (i) newly diagnosed therapy-related acute myeloid leukaemia (AML), (ii) newly diagnosed AML with myelodysplasia-related changes (MRC) (prior myelodysplastic syndromes (MDS) or MDS-related cytogenetic or molecular abnormality); AND The condition must not be either: (i) internal tandem duplication (ITD); (ii) tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3), mutation positive; AND Patient must not have favourable cytogenetic risk acute myeloid leukaemia (AML); AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND	Compliance with Authority Required procedures

				The treatment must not exceed two cycles of induction therapy under this restriction. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. The prescriber must confirm whether the patient has newly diagnosed therapy-related AML or AML-MRC. The test result and date of testing must be provided at the time of application and documented in the patient's file. The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information. Each prescription must include the amount of daunorubicin with cytarabine (Vyxeos) that is appropriate to be prescribed for the patient. For the purposes of the authority application, the maximum amount requested is based on the daunorubicin dose only. The prescribed amount of daunorubicin must be expressed in milligrams.	
C16188	P16188	CN16188	Nivolumab with relatlimab	Unresectable Stage III or Stage IV malignant melanoma Initial treatment Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; AND Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND The condition must not be uveal melanoma; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must weigh 40 kg or more; AND Patient must be at least 12 years of age. Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen. The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information. The prescription must include the amount of nivolumab with relatlimab (Opdualag) that is appropriate to be prescribed for the patient. For the purposes of PBS subsidy, the maximum amount requested is based on the nivolumab dose only. The prescribed amount of nivolumab must be expressed in milligrams.	Compliance with Authority Required procedures - Streamlined Authority Code 16188
C16189	P16189	CN16189	Methylphenidate	Attention deficit hyperactivity disorder Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events; AND Patient must require continuous coverage over 12 hours; AND	Compliance with Authority Required procedures

				The treatment must not exceed a maximum daily dose of 72 mg of PBS-subsidised treatment with this drug. Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive.	
C16190	P16190	CN16190	Molnupiravir	SARS-CoV-2 infection The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated; AND Patient must have received a positive nucleic acid test result; OR Patient must have received a positive rapid antigen test (RAT) result; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND The treatment must be initiated within 5 days of symptom onset; OR The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic. Patient must be at least 70 years of age. Access to this drug through this restriction is permitted irrespective of vaccination status. Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record. Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record. This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection. For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid. Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 16190
C16191	P16191	CN16191	Molnupiravir	SARS-CoV-2 infection The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated; AND Patient must have received a positive nucleic acid test result; OR Patient must have received a positive rapid antigen test (RAT) result; AND Patient must have at least one sign or symptom attributable to COVID-19; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND Patient must satisfy at least one of the following criteria: (i) be moderately to severely immunocompromised with risk of progression to severe COVID-19 disease due to the	Compliance with Authority Required procedures - Streamlined Authority Code 16191

	immunocompromised status, (ii) has experienced past COVID-19 infection resulting in hospitalisation; AND The treatment must be initiated within 5 days of symptom onset. Patient must be at least 18 years of age. For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with: 1. Any primary or acquired immunodeficiency including: a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders, b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months), c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR 2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received: a. Chemotherapy or whole body radiotherapy, b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy, c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin), d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR 3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR 4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR 5. People with disability with multiple comorbidities and/or frailty. Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell. Access to this drug through this restriction is permitted irrespective of vaccination status.	

				Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record. Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record. This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection. For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid. Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.	
C16192	P16192	CN16192	Nirmatrelvir and ritonavir	SARS-CoV-2 infection Patient must have received a positive nucleic acid test result; OR Patient must have received a positive rapid antigen test (RAT) result; AND Patient must have at least one sign or symptom attributable to COVID-19; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND The treatment must be initiated within 5 days of symptom onset. Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk. For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions: 1. The patient is in residential aged care 2. The patient has disability with multiple comorbidities and/or frailty 3. Neurological conditions, including stroke and dementia and demyelinating conditions 4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease 5. Heart failure, coronary artery disease, cardiomyopathies 6. Obesity (BMI greater than 30 kg/m ^{2}) 7. Diabetes type I or II, requiring medication for glycaemic control 8. Renal impairment (eGFR less than 60mL/min) 9. Cirrhosis 10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above 11. Past COVID-19 infection episode resulting in hospitalisation.	Compliance with Authority Required procedures - Streamlined Authority Code 16192

				Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records. For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell. Access to this drug through this restriction is permitted irrespective of vaccination status. Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record. Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record. This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.	
C16194	P16194	CN16194	Testosterone	Constitutional delay of growth or puberty Patient must be under 18 years of age. Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The treatment must be applied to the scrotum, where possible. The name of the specialist must be included in the authority application.	Compliance with Authority Required procedures
C16195	P16195	CN16195	Testosterone	Constitutional delay of growth or puberty The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must be under 18 years of age. Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The treatment must be applied to the scrotum, where possible. The name of the specialist must be included in the authority application.	Compliance with Authority Required procedures
C16197	P16197	CN16197	Daunorubicin with cytarabine	Acute Myeloid Leukaemia Consolidation therapy The treatment must be for consolidation treatment following induction treatment with this product; AND	Compliance with Authority Required procedures

				The condition must be either: (i) newly diagnosed therapy-related acute myeloid leukaemia (AML), (ii) newly diagnosed AML with myelodysplasia-related changes (MRC) (prior myelodysplastic syndromes (MDS) or MDS-related cytogenetic or molecular abnormality); AND The treatment must not exceed two cycles of consolidation therapy under this restriction. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information. Each prescription must include the amount of daunorubicin with cytarabine (Vyxeos) that is appropriate to be prescribed for the patient. For the purposes of the authority application, the maximum amount requested is based on the daunorubicin dose only. The prescribed amount of daunorubicin must be expressed in milligrams.	
C16200	P16200	CN16200	Molnupiravir	SARS-CoV-2 infection The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated; AND Patient must have received a positive nucleic acid test result; OR Patient must have received a positive rapid antigen test (RAT) result; AND Patient must have at least one sign or symptom attributable to COVID-19; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND The treatment must be initiated within 5 days of symptom onset. Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk. For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions: 1. The patient is in residential aged care 2. The patient has disability with multiple comorbidities and/or frailty 3. Neurological conditions, including stroke and dementia and demyelinating conditions 4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease 5. Heart failure, coronary artery disease, cardiomyopathies 6. Obesity (BMI greater than 30 kg/m ^{2}) 7. Diabetes type I or II, requiring medication for glycaemic control 8. Renal impairment (eGFR less than 60mL/min) 9. Cirrhosis	Compliance with Authority Required procedures - Streamlined Authority Code 16200

				10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above 11. Past COVID-19 infection episode resulting in hospitalisation. Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records. For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell. Access to this drug through this restriction is permitted irrespective of vaccination status. Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record. Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record. This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection. For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid. Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.	
C16201	P16201	CN16201	Molnupiravir	SARS-CoV-2 infection The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated; AND Patient must have received a positive nucleic acid test result; OR Patient must have received a positive rapid antigen test (RAT) result; AND Patient must have at least one sign or symptom attributable to COVID-19; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND The treatment must be initiated within 5 days of symptom onset. Patient must be both: (i) at least 50 years of age, (ii) at high risk. For the purpose of administering this restriction, high risk is defined as either a past COVID-19 infection episode resulting in hospitalisation, or the presence of at least two of the following conditions: 1. The patient is in residential aged care, 2. The patient has disability with multiple comorbidities and/or frailty,	Compliance with Authority Required procedures - Streamlined Authority Code 16201

				3. Neurological conditions, including stroke and dementia and demyelinating conditions, 4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease, 5. Heart failure, coronary artery disease, cardiomyopathies, 6. Obesity (BMI greater than 30 kg/m ^{2}), 7. Diabetes type I or II, requiring medication for glycaemic control, 8. Renal impairment (eGFR less than 60mL/min), 9. Cirrhosis, or 10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above. Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records. For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell. Access to this drug through this restriction is permitted irrespective of vaccination status. Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record. Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record. This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection. For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid. Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.	
C16204	P16204	CN16204	Testosterone	Micropenis Patient must be under 18 years of age. Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.	Compliance with Authority Required procedures

				The treatment must be applied to the scrotum, where possible. The name of the specialist must be included in the authority application.	
C16206	P16206	CN16206	Testosterone	Micropenis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must be under 18 years of age. Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The treatment must be applied to the scrotum, where possible. The name of the specialist must be included in the authority application.	Compliance with Authority Required procedures
C16207	P16207	CN16207	Testosterone	Pubertal induction The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must be under 18 years of age. Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The treatment must be applied to the scrotum, where possible. The name of the specialist must be included in the authority application.	Compliance with Authority Required procedures
C16208	P16208	CN16208	Belzutifan	Von Hippel-Lindau (VHL) disease Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangement Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2024; AND The condition must have been diagnosed by at least one of: (i) a germline VHL alteration; (ii) at least two manifestations highly characteristic of VHL disease; (iii) at least one manifestation highly characteristic of VHL disease with a documented family history of VHL; AND The condition must have been at least one of the following prior to non-PBS-subsidised treatment with this drug: (i) VHL-associated non-metastatic renal cell carcinoma (RCC); (ii) VHL-associated central nervous system (CNS) haemangioblastoma; (iii) VHL-associated non-metastatic pancreatic neuroendocrine tumour (pNET); AND Patient must not have had tumour(s) that require immediate surgery as assessed by the treating clinician prior to non-PBS-subsidised treatment with this drug; AND	Compliance with Authority Required procedures

				Patient must have had a WHO performance status score of no greater than 1 at treatment initiation with this drug; OR The condition must have been VHL-associated brain stem tumour(s), or brain herniation, which temporarily affected the patient's WHO performance status to be higher than 1 at treatment initiation with this drug; AND Patient must not have developed VHL-associated metastatic disease; AND Patient must have demonstrated clinical improvement or stabilisation of the condition, the details of which must be kept with the patient's record. This should be assessed only after a total of 6 months of therapy. Must be treated by a physician with expertise in the management of VHL disease associated tumours. Patients who cease therapy for reasons other than, clinical disease progression or metastasis, may re-initiate PBS-subsidised treatment through the initiating or recommencing treatment phase. For the purpose of administering this restriction, the highly characteristic manifestations of VHL disease include but not limited to: (i) retinal, spinal, or cerebellar haemangioblastoma; (ii) adrenal or extra-adrenal phaeochromocytoma; (iii) renal cell carcinoma; (iv) multiple renal and pancreatic cysts; (v) endolymphatic sac tumours, papillary cystadenomas of the epididymis or broad ligament, or pancreatic neuroendocrine tumours. For the purpose of administering this restriction, clinical improvement or stabilisation of the patient's condition includes but is not limited to: (i) avoidance of surgery; (ii) avoidance of renal replacement therapy such as dialysis or renal transplantation in patients with VHL- associated renal cell carcinoma (RCC); (iii) experiencing clinical benefit in at least one of the VHL associated conditions, as determined by the treating clinician(s). A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.	
C16211	P16211	CN16211	Testosterone	Androgen deficiency Patient must not have an established pituitary or testicular disorder; AND The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs. Patient must be aged 40 years or older.	Compliance with Authority Required procedures

				Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The treatment must be applied to the scrotum, where possible. Androgen deficiency is defined as: (i) testosterone level of less than 6 nmol per litre; OR (ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher). Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings. The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated. The name of the specialist must be included in the authority application.	
C16212	P16212	CN16212	Testosterone	Pubertal induction Patient must be under 18 years of age. Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The treatment must be applied to the scrotum, where possible. The name of the specialist must be included in the authority application.	Compliance with Authority Required procedures
C16214	P16214	CN16214	Testosterone	Androgen deficiency The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must not have an established pituitary or testicular disorder; AND The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs. Patient must be aged 40 years or older. Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The treatment must be applied to the scrotum, where possible. Androgen deficiency is defined as: (i) testosterone level of less than 6 nmol per litre; OR	Compliance with Authority Required procedures

				(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher). Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings. The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated. The name of the specialist must be included in the authority application.	
C16215	P16215	CN16215	Belzutifan	Von Hippel-Lindau (VHL) disease Initiating or recommencing treatment The condition must have been diagnosed by at least one of: (i) a germline VHL alteration; (ii) at least two manifestations highly characteristic of VHL disease; (iii) at least one manifestation highly characteristic of VHL disease with a documented family history of VHL; AND The condition must be at least one of: (i) VHL-associated non-metastatic renal cell carcinoma (RCC); (ii) VHL-associated central nervous system (CNS) haemangioblastoma; (iii) VHL-associated non-metastatic pancreatic neuroendocrine tumour (pNET); AND Patient must not have tumour(s) that require immediate surgery as assessed by the treating clinician; AND Patient must be untreated with this drug for this condition; OR Patient must have previously received PBS-subsidised treatment with this drug for this condition for a different tumour type; OR Patient must have previously received PBS-subsidised treatment with this drug for this condition and ceased previous treatment for family planning purposes; AND Patient must have WHO performance status no higher than 1; OR The condition must be VHL-associated brainstem tumour(s), or brain herniation, which temporarily affected the patient's WHO performance status to be higher than 1; AND The treatment must be the sole PBS-subsidised therapy for VHL disease associated tumours. Must be treated by a physician with expertise in the management of VHL disease associated tumours. Patients who cease therapy for reasons other than, clinical disease progression or metastasis, may re-initiate PBS-subsidised treatment through the initiating or recommencing treatment phase. For the purpose of administering this restriction, the highly characteristic manifestations of VHL disease include but not limited to: (i) retinal, spinal, or cerebellar haemangioblastoma;	Compliance with Authority Required procedures

				(ii) adrenal or extra-adrenal phaeochromocytoma; (iii) renal cell carcinoma; (iv) multiple renal and pancreatic cysts; (v) endolymphatic sac tumours, papillary cystadenomas of the epididymis or broad ligament, or pancreatic neuroendocrine tumours.	
C16220	P16220	CN16220	Dapagliflozin	Diabetes mellitus type 2 The treatment must be in combination with metformin; unless contraindicated/intolerant; AND Patient must have cardiovascular disease; OR Patient must be at high risk of a cardiovascular event; OR Patient must identify as Aboriginal or Torres Strait Islander. Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 16220
C16222	P16222	CN16222	Dienogest	Endometriosis	Compliance with Authority Required procedures - Streamlined Authority Code 16222
C16223	P16223	CN16223	Nirmatrelvir and ritonavir	SARS-CoV-2 infection Patient must have received a positive nucleic acid test result; OR Patient must have received a positive rapid antigen test (RAT) result; AND Patient must have at least one sign or symptom attributable to COVID-19; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND Patient must satisfy at least one of the following criteria: (i) be moderately to severely immunocompromised with risk of progression to severe COVID-19 disease due to the immunocompromised status, (ii) has experienced past COVID-19 infection resulting in hospitalisation; AND The treatment must be initiated within 5 days of symptom onset. Patient must be at least 18 years of age. For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with: 1. Any primary or acquired immunodeficiency including: a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders, b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months), c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR	Compliance with Authority Required procedures - Streamlined Authority Code 16223

		2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received: a. Chemotherapy or whole body radiotherapy, b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy, c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin), d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR 3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR 4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR 5. People with disability with multiple comorbidities and/or frailty. Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell. Access to this drug through this restriction is permitted irrespective of vaccination status. Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record. Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record. This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

[132] Schedule 4, Part 2, omit entry for Variation Code “V14812”

[133] Schedule 4, Part 2, omit entry for Variation Code “V14815”

[134] Schedule 4, Part 2, omit entry for Variation Code "V14819"

[135] Schedule 4, Part 2, omit entry for Variation Code "V14829"

[136] Schedule 5, after entry for Abacavir with lamivudine

insert:

Abiraterone	GRP-29273	Tablet containing abiraterone acetate 250 mg	Oral	Abiraterone-Teva Zytiga
Abiraterone	GRP-29283	Tablet containing abiraterone acetate 500 mg	Oral	Abiraterone-Teva Zytiga

[137] Schedule 5, after entry for Atorvastatin *[GRP-20251]*

insert:

Atovaquone	GRP-29277	Oral suspension 750 mg per 5 mL, 210 mL	Oral	ATOVACUE Wellvone

[138] Schedule 5, after entry for Buprenorphine *[GRP-24293]*

insert:

Cabergoline	GRP-19705	Tablet 500 micrograms	Oral	Dostamine Dostinex

[139] Schedule 5, after entry for Clonazepam

insert:

Clonazepam	GRP-29271	Tablet 2 mg	Oral	Paxam 2
Clonazepam	GRP-29271	Tablet 2 mg (S19A)	Oral	Clonazepam USP (Advagen Pharma, USA)

[140] Schedule 5, entries for Dasatinib

substitute:

Dasatinib	GRP-25848	Tablet 70 mg	Oral	Dasatinib ARX Dasatinib Dr.Reddy's Dasatinib Sandoz

				Dasatinib SUN DASATINIB-TEVA Dasatinib Viatris Sprycel
Dasatinib	GRP-25849	Tablet 20 mg	Oral	Dasatinib ARX Dasatinib Dr.Reddy's Dasatinib Sandoz Dasatinib SUN DASATINIB-TEVA Dasatinib Viatris Sprycel
Dasatinib	GRP-25853	Tablet 50 mg	Oral	Dasatinib ARX Dasatinib Dr.Reddy's Dasatinib Sandoz Dasatinib SUN DASATINIB-TEVA Dasatinib Viatris Sprycel
Dasatinib	GRP-25880	Tablet 100 mg	Oral	Dasatinib ARX Dasatinib Dr.Reddy's Dasatinib Sandoz Dasatinib SUN DASATINIB-TEVA Dasatinib Viatris Sprycel

[141] Schedule 5, entry for Dutasteride with tamsulosin

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

[142] Schedule 5, omit entries for Epoprostenol

[143] Schedule 5, entry for Ezetimibe

substitute:

Ezetimibe	GRP-29270	Tablet 10 mg	Oral	APO-Ezetimibe BTC Ezetimibe EZEMICHOL EZETIMIBE-WGR Ezetimibe GH Ezetimibe Sandoz

				Ezetrol Pharmacor Ezetimibe 10 Zient 10mg
Ezetimibe	GRP-29270	Tablet 10 mg (S19A)	Oral	Ezetimibe USP (Camber, USA)

[144] Schedule 5, entries for Gabapentin

substitute:

Gabapentin	GRP-20038	Capsule 100 mg	Oral	APX-Gabapentin Gabacor GAPENTIN Neurontin Nupentin 100
Gabapentin	GRP-20075	Tablet 600 mg	Oral	APX-GABAPENTIN Gabapentin APOTEX GAPENTIN Neurontin Pharmacor Gabapentin 600
Gabapentin	GRP-20089	Tablet 800 mg	Oral	GAPENTIN Gabapentin APOTEX Neurontin Pharmacor Gabapentin 800
Gabapentin	GRP-20136	Capsule 300 mg	Oral	APX-Gabapentin Gabacor Gabapentin Sandoz GABAPENTIN-WGR GAPENTIN Neurontin Nupentin 300
Gabapentin	GRP-20293	Capsule 400 mg	Oral	APX-Gabapentin Gabacor Gabapentin Sandoz GABAPENTIN-WGR GAPENTIN Neurontin Nupentin 400

[145] Schedule 5, entry for Ibuprofen

insert in the column headed "Brand" after entry for the Brand "Brufen": WGR-IBUPROFEN 400

[146] Schedule 5, omit entry for Ketoprofen

[147] Schedule 5, omit entries for Medroxyprogesterone *[GRP-28650]*

[148] Schedule 5, entry for Metformin *[GRP-19880]*

substitute:

Metformin	GRP-19880	Tablet containing metformin hydrochloride 500 mg	Oral	APX-Metformin Blooms The Chemist Metformin 500 mg Diabex Diaformin Diaformin Viatris FORMET 500 Glucobete 500 Metformin GH Metformin Sandoz METFORMIN-WGR

[149] Schedule 5, entry for Metformin *[GRP-19944]*

insert in the column headed "Brand" after entry for the Brand "Metformin Sandoz": METFORMIN-WGR

[150] Schedule 5, after entry for Methadone *[GRP-27523]*

insert:

Methadone	GRP-29269	Tablet containing methadone hydrochloride 10 mg	Oral	METHADONE-AFT Physeptone

[151] Schedule 5, omit entry for Nevirapine

[152] Schedule 5, entry for Olmesartan with amlodipine *[GRP-21157]*

insert as the first entry in the column headed "Brand": APO-OLMESARTAN/AMLODIPINE 40/10

[153] Schedule 5, entry for Pioglitazone *[GRP-19790]*

substitute:

Pioglitazone	GRP-19790	Tablet 45 mg (as hydrochloride)	Oral	Actos APOTEX-Pioglitazone ARX-PIOGLITAZONE Vexazone

[154] Schedule 5, entries for Prochlorperazine

omit:

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

[155] Schedule 5, entry for Rivaroxaban *[GRP-29154]*

insert in the column headed "Brand" after entry for the Brand "Rivaroxaban-Teva": RIVOXA

[156] Schedule 5, entry for Rivaroxaban *[GRP-29169]*

(a) insert in the column headed "Brand" after entry for the Brand "iXarola": Rivaroxaban Sandoz

(b) insert in the column headed "Brand" after entry for the Brand "Rivaroxaban-Teva": RIVOXA

[157] Schedule 5, entry for Rivaroxaban *[GRP-29173]*

(a) insert in the column headed "Brand" after entry for the Brand "iXarola": Rivaroxaban Sandoz

(b) insert in the column headed "Brand" after entry for the Brand "Rivaroxaban-Teva": RIVOXA

[158] Schedule 5, entry for Rivaroxaban *[GRP-29164]*

(a) insert in the column headed "Brand" after entry for the Brand "iXarola": Rivaroxaban Sandoz

(b) insert in the column headed "Brand" after entry for the Brand "Rivaroxaban-Teva": RIVOXA

[159] Schedule 5, entry for Rizatriptan in the form Tablet (orally disintegrating) 10 mg (as benzoate)

insert as the first entry in the column headed "Brand": APO-RIZATRIPTAN ODT

[160] Schedule 5, entries for Varenicline

substitute:

Varenicline	GRP-26245	Tablet 1 mg	Oral	Champix PHARMACOR VARENICLINE VARENAPIX Varenicline Sandoz Varenicline Viatris

Varenicline	GRP-27996	Box containing 11 tablets 0.5 mg and 42 tablets 1 mg	Oral	Champix PHARMACOR VARENICLINE VARENAPIX Varenicline Sandoz Varenicline Viatris