PB 104 of 2019

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2019 (No. 12)

National Health Act 1953

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

Dated 20th December 2019

THEA DANIEL
Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health

Authorised Version F2019L01690 registered 23/12/2019

1 Name of Instrument

(1) This Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2019 (No. 12)*.

(2) This Instrument may also be cited as PB 104 of 2019.

2 Commencement

This Instrument commences on 1 January 2020.

3 Amendment of *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012)

Schedule 1 amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012).

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Schedule 1 Amendments

[1] Schedule 1, entry for Abacavir with lamivudine in the form Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg

omit:

			Abacavir/Lamivudine 600/300 APOTEX	TX	MP	C4527 C4528	60	5	30	D(100)

[2] Schedule 1, after entry for Abatacept in the form Powder for I.V. infusion 250 mg

insert:

Abemaciclib	Tablet 50 mg	Oral	Verzenio	LY	MP	C10019 C10032	56	5	56
	Tablet 100 mg	Oral	Verzenio	LY	MP	C10019 C10032	56	5	56
	Tablet 150 mg	Oral	Verzenio	LY	MP	C10019 C10032	56	5	56

[3] Schedule 1, entry for Alprazolam in each of the forms: Tablet 500 micrograms; and Tablet 1 mg

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[4] Schedule 1, entry for Amoxicillin with clavulanic acid in the form Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)

omit from the column headed "Responsible Person" for the brand "Moxiclav Duo 500/125" (all instances): **QA** *substitute:* **LN**

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

omit from the column headed "Responsible Person" for the brand "Moxiclav Duo Forte 875/125" (all instances): **QA** *substitute:* **LN**

[6] Schedule 1, entry for Amphotericin B

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[7] Schedule 1, entry for Anastrozole

omit from the column headed "Responsible Person" for the brand "Anastrol": **QA** *substitute:* **AS**

[8] Schedule 1, entry for Atorvastatin in each of the forms: Tablet 10 mg (as calcium); Tablet 20 mg (as calcium); Tablet 40 mg (as calcium); and Tablet 80 mg (as calcium)

(a) *omit:*

		a	Atorvastatin Sandoz	SZ	MP NP		30	5	30	

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(b) *omit:*

	a	Atorvastatin Sandoz	SZ	MP		P7598	30	11	30

[9] Schedule 1, entry for Atropine in the form Eye drops containing atropine sulfate monohydrate 10 mg per mL, 15 mL

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[10] Schedule 1, entry for Avelumab

(a) *omit from the column headed "Circumstances":* **C8856**

(b) *insert in numerical order in the column headed "Circumstances":* **C10023**

[11] Schedule 1, entry for Azacitidine

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

	a	Azacitidine-Teva	TB	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

[12] Schedule 1, entry for Betamethasone in the form Cream 200 micrograms (as valerate) per g, 100 g

(a) *omit from the column headed "Responsible Person" for the brand "Betnovate 1/5":* **QA** *substitute:* **AS**

(b) *omit from the column headed "Responsible Person" for the brand "Cortival 1/5":* **FM** *substitute:* **LN**

[13] Schedule 1, entry for Betamethasone in the form Cream 500 micrograms (as valerate) per g, 15 g

(a) *omit from the column headed "Responsible Person" for the brand "Betnovate 1/2" (all instances):* **QA** *substitute:* **AS**

(b) *omit from the column headed "Responsible Person" for the brand "Cortival 1/2" (all instances):* **FM** *substitute:* **LN**

[14] Schedule 1, entry for Bicalutamide

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[15] Schedule 1, entry for Bimatoprost in the form Eye drops 300 micrograms per mL, 3 mL

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[16] Schedule 1, entry for Budesonide in the form Rectal foam 2 mg per application, 14 applications, aerosol 16.8 g, 2

omit from the column headed "Responsible Person": **OA** *substitute:* **FD**

[17] Schedule 1, entry for Capecitabine in the form Tablet 500 mg

(a) *omit:*

	a	Capecitabine Apotex	TX	MP			120	2	120

(b) *omit from the column headed "Responsible Person" for the brand "Xelabine":* **QA** *substitute:* **AS**

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[18] **Schedule 1, entry for Chloramphenicol**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[19] **Schedule 1, entry for Cladribine in the form Injection 10 mg in 5 mL**

omit from the column headed "Responsible Person": **OA** *substitute:* **AS**

[20] **Schedule 1, entry for Cobimetinib in the form Tablet 20 mg *[Maximum Quantity: 63; Number of Repeats: 3]***

(a) *omit from the column headed "Circumstances":* **C6839**

(b) *insert in numerical order in the column headed "Circumstances":* **C10033**

(c) *omit from the column headed "Purposes":* **P6839** *substitute:* **P10033**

[21] **Schedule 1, entry for Cobimetinib in the form Tablet 20 mg *[Maximum Quantity: 63; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C6839**

(b) *insert in numerical order in the column headed "Circumstances":* **C10033**

[22] **Schedule 1, entry for Codeine**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[23] **Schedule 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg**

omit from the column headed "Responsible Person" for the brand "Cyprocur 50" (all instances): **QA** *substitute:* **AS**

[24] **Schedule 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 100 mg**

omit from the column headed "Responsible Person" for the brand "Cyprocur 100": **QA** *substitute:* **AS**

[25] **Schedule 1, entry for Dexamfetamine**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[26] **Schedule 1, entry for Digoxin in the form Paediatric oral solution 50 micrograms per mL, 60 mL**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[27] **Schedule 1, entry for Digoxin in the form Tablet 62.5 micrograms**

(a) *omit from the column headed "Responsible Person":* **QA** *substitute:* **AS**

(b) *omit from the column headed "Responsible Person":* **FM** *substitute:* **LN**

[28] **Schedule 1, entry for Digoxin in the form Tablet 250 micrograms**

(a) *omit from the column headed "Responsible Person":* **QA** *substitute:* **AS**

(b) *omit from the column headed "Responsible Person":* **FM** *substitute:* **LN**

[29] **Schedule 1, entry for Dorzolamide**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

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[30] **Schedule 1, entry for Dorzolamide with timolol**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[31] **Schedule 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-10 mg**

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

		a	EzSimva GH 10/10	GQ	MP NP	C7958		30	5	30	

[32] **Schedule 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-20 mg**

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

		a	EzSimva GH 10/20	GQ	MP NP	C7958		30	5	30	

[33] **Schedule 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-40 mg**

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

		a	EzSimva GH 10/40	GQ	MP NP	C7957		30	5	30	

[34] **Schedule 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-80 mg**

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

		a	EzSimva GH 10/80	GQ	MP NP	C7957		30	5	30	

[35] **Schedule 1, entry for Fluconazole**

omit:

	Solution for I.V. infusion 100 mg in 50 mL	Injection	Fluconazole Sandoz	SZ	MP NP	C5978 C5989 C6002 C6023 C6030 C7898		7	0	1	

[36] **Schedule 1, entry for Fludrocortisone**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[37] **Schedule 1, entry for Follitropin alfa with lutropin alfa**

omit:

	Powder for injection 150 I.U.-75 I.U. with solvent	Injection	Pergoveris	SG	MP	C5250		14	0	1	D(100)

[38] **Schedule 1, entry for Griseofulvin in each of the forms: Tablet 125 mg; and Tablet 500 mg**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

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[39] **Schedule 1, entry for Haloperidol in each of the forms: Injection 5 mg in 1 mL; Oral solution 2 mg per mL, 100 mL; Tablet 500 micrograms; Tablet 1.5 mg; and Tablet 5 mg**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[40] **Schedule 1, entry for Hydrocortisone in the form Cream containing hydrocortisone acetate 10 mg per g, 50 g**

(a) *omit from the column headed "Responsible Person" for the brand "Cortic-DS 1%" (all instances):* **FM** *substitute:* **LN**

(b) *omit from the column headed "Responsible Person" for the brand "Sigmacort" (all instances):* **QA** *substitute:* **AS**

[41] **Schedule 1, entry for Hydrocortisone in the form Eye ointment containing hydrocortisone acetate 10 mg per g, 5 g**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[42] **Schedule 1, entry for Hydrocortisone in the form Ointment containing hydrocortisone acetate 10 mg per g, 50 g**

(a) *omit from the column headed "Responsible Person" for the brand "Cortic-DS 1%" (all instances):* **FM** *substitute:* **LN**

(b) *omit from the column headed "Responsible Person" for the brand "Sigmacort" (all instances):* **QA** *substitute:* **AS**

[43] **Schedule 1, entry for Hypromellose in the form Eye drops 5 mg per mL, 15 mL**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[44] **Schedule 1, entry for Imatinib in the form Capsule 100 mg (as mesilate)** ***[Maximum Quantity: 60; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances" (all instances):* **C6510 C6526 C6538 C6557**

(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C10010 C10026 C10035 C10048**

(c) *omit from the column headed "Purposes" (all instances):* **P6510 P6526 P6538 P6557**

(d) *insert in numerical order in the column headed "Purposes" (all instances):* **P10010 P10026 P10035 P10048**

[45] **Schedule 1, entry for Imatinib in the form Capsule 100 mg (as mesilate)** ***[Maximum Quantity: 60; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances" (all instances):* **C6510 C6526 C6538 C6557**

(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C10010 C10026 C10035 C10048**

[46] **Schedule 1, entry for Imatinib in the form Capsule 400 mg (as mesilate)** ***[Maximum Quantity: 30; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances" (all instances):* **C6510 C6526 C6538 C6557**

(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C10010 C10026 C10035 C10048**

(c) *omit from the column headed "Purposes" (all instances):* **P6510 P6526 P6538 P6557**

(d) *insert in numerical order in the column headed "Purposes" (all instances):* **P10010 P10026 P10035 P10048**

[47] **Schedule 1, entry for Imatinib in the form Capsule 400 mg (as mesilate)** ***[Maximum Quantity: 30; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances" (all instances):* **C6510 C6526 C6538 C6557**

(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C10010 C10026 C10035 C10048**

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

(a) *omit from the column headed "Circumstances" (all instances):* **C6510 C6526 C6538 C6557**

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(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C10010 C10026 C10035 C10048**

(c) *omit from the column headed "Purposes" (all instances):* **P6510 P6526 P6538 P6557**

(d) *insert in numerical order in the column headed "Purposes" (all instances):* **P10010 P10026 P10035 P10048**

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

(a) *omit from the column headed "Circumstances" (all instances):* **C6510 C6526 C6538 C6557**

(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C10010 C10026 C10035 C10048**

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

(a) *omit from the column headed "Circumstances" (all instances):* **C6510 C6526 C6538 C6557**

(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C10010 C10026 C10035 C10048**

(c) *omit from the column headed "Purposes" (all instances):* **P6510 P6526 P6538 P6557**

(d) *insert in numerical order in the column headed "Purposes" (all instances):* **P10010 P10026 P10035 P10048**

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

(a) *omit from the column headed "Circumstances" (all instances):* **C6510 C6526 C6538 C6557**

(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C10010 C10026 C10035 C10048**

[52] Schedule 1, entry for Insulin glargine in the form Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5

(a) *insert in the column headed "Schedule Equivalent" for the brand "Lantus":* **b**

(b) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

b	Optisulin	GZ	MP NP	5	1	1

(c) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

a	Optisulin SoloStar	WA	MP NP	5	1	1

[53] Schedule 1, entry for Ipratropium in each of the forms: Nebuliser solution containing ipratropium bromide 250 micrograms (as monohydrate) in 1 mL single dose units, 30; and Nebuliser solution containing ipratropium bromide 500 micrograms (as monohydrate) in 1 mL single dose units, 30

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[54] Schedule 1, entry for Labetalol in each of the forms: Tablet containing labetalol hydrochloride 100 mg; and Tablet containing labetalol hydrochloride 200 mg

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[55] Schedule 1, entry for Latanoprost

omit from the column headed "Responsible Person" for the brand "Xalaprost": **QA** *substitute:* **AS**

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[56] **Schedule 1, entry for Latanoprost with timolol**

omit from the column headed "Responsible Person" for the brand "Xalamol 50/5": **QA** *substitute:* **AS**

[57] **Schedule 1, entry for Letrozole**

omit from the column headed "Responsible Person" for the brand "Fera": **QA** *substitute:* **AS**

[58] **Schedule 1, entry for Levothyroxine in each of the forms: Tablet containing 50 micrograms anhydrous levothyroxine sodium; Tablet containing 75 micrograms anhydrous levothyroxine sodium; Tablet containing 100 micrograms anhydrous levothyroxine sodium; and Tablet containing 200 micrograms anhydrous levothyroxine sodium**

(a) *omit from the column headed "Responsible Person" for the brand "Eutroxsig":* **FM** *substitute:* **LN**

(b) *omit from the column headed "Responsible Person" for the brand "Oroxine":* **QA** *substitute:* **AS**

[59] **Schedule 1, entry for Liothyronine**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[60] **Schedule 1, entry for Mesalazine in each of the forms: Enemas 2 g in 60 mL, 7; Enemas 4 g in 60 mL, 7; Rectal foam 1 g per applicatorful, 14 applications, aerosol 80 g; Sachet containing granules, 500 mg per sachet; and Sachet containing granules, 1 g per sachet**

omit from the column headed "Responsible Person": **OA** *substitute:* **FD**

[61] **Schedule 1, entry for Mesalazine in the form Sachet containing granules, 1.5 g per sachet**

omit from the column headed "Responsible Person": **OA** *substitute:* **FD**

[62] **Schedule 1, entry for Mesalazine in the form Sachet containing granules, 3 g per sachet**

omit from the column headed "Responsible Person": **OA** *substitute:* **FD**

[63] **Schedule 1, entry for Mesalazine in the form Suppository (moulded) 1 g**

omit from the column headed "Responsible Person": **OA** *substitute:* **FD**

[64] **Schedule 1, entry for Mesalazine in the form Tablet 500 mg (enteric coated)**

omit from the column headed "Responsible Person": **OA** *substitute:* **FD**

[65] **Schedule 1, entry for Mesalazine in the form Tablet 1 g (enteric coated)**

omit from the column headed "Responsible Person": **OA** *substitute:* **FD**

[66] **Schedule 1, entry for Metformin in the form Tablet containing metformin hydrochloride 500 mg**

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

a	Metformin GH	HQ	MP NP	100	5	100	

[67] **Schedule 1, entry for Methadone in the form Injection containing methadone hydrochloride 10 mg in 1 mL**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

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[68] **Schedule 1, entry for Methadone in the form Oral liquid containing methadone hydrochloride 25 mg per 5 mL, 1 L**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[69] **Schedule 1, entry for Methadone in the form Oral liquid containing methadone hydrochloride 25 mg per 5 mL, 200 mL**

omit from the column headed "Responsible Person" for the brand "Aspen Methadone Syrup" (all instances): **QA** *substitute:* **AS**

[70] **Schedule 1, entry for Methadone in the form Tablet containing methadone hydrochloride 10 mg**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[71] **Schedule 1, entry for Methylprednisolone in the form Fatty ointment containing methylprednisolone aceponate 1 mg per g, 15 g**

omit from the column headed "Brand": **Advantan** *substitute:* **Advantan (Fatty)**

[72] **Schedule 1, entry for Minocycline**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[73] **Schedule 1, entry for Mometasone in the form Cream containing mometasone furoate 1 mg per g, 15 g**

omit from the column headed "Responsible Person" for the brand "Momasone" (all instances): **QA** *substitute:* **AS**

[74] **Schedule 1, entry for Mometasone in the form Lotion containing mometasone furoate 1 mg per g, 30 mL**

omit from the column headed "Responsible Person" for the brand "Momasone" (all instances): **QA** *substitute:* **AS**

[75] **Schedule 1, entry for Mometasone in the form Ointment containing mometasone furoate 1 mg per g, 15 g**

omit from the column headed "Responsible Person" for the brand "Momasone" (all instances): **QA** *substitute:* **AS**

[76] **Schedule 1, entry for Morphine**

omit:

	Injection containing morphine tartrate 120 mg in 1.5 mL	Injection	Hospira Pty Limited	PF	MP NP	5	0	5	

[77] **Schedule 1, entry for Nevirapine in the form Tablet 200 mg**

(a) *omit from the column headed "Schedule Equivalent" for the brand "Nevirapine Alphapharm":* **a**

(b) *omit:*

	a	Viramune	BY	MP	C4454 C4512	120	5	60	D(100)

[78] **Schedule 1, entry for Nicorandil in each of the forms: Tablets 10 mg, 60; and Tablets 20 mg, 60**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[79] **Schedule 1, entry for Nystatin in the form Capsule 500,000 units**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

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[80] **Schedule 1, entry for Nystatin in the form Cream 100,000 units per g, 15 g**

omit from the column headed "Responsible Person": **FM** *substitute:* **LN**

[81] **Schedule 1, entry for Nystatin in the form Tablet 500,000 units**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[82] **Schedule 1, entry for Oxazepam in the form Tablet 15 mg**

omit from the column headed "Responsible Person" for the brand "Serepax" (all instances): **QA** *substitute:* **AS**

[83] **Schedule 1, entry for Oxazepam in the form Tablet 30 mg**

omit from the column headed "Responsible Person" for the brand "Serepax" (all instances): **QA** *substitute:* **AS**

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

omit from the column headed "Circumstances": **C9003 C9008 C9009** *substitute:* **C10013 C10015 C10043**

[85] **Schedule 1, entry for Perhexiline**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[86] **Schedule 1, entry for Phenobarbital in the form Injection 200 mg (as sodium) in 1 mL**

omit from the column headed "Responsible Person": **FM** *substitute:* **AS**

[87] **Schedule 1, entry for Phenoxymethylpenicillin in the form Oral suspension 150 mg (as benzathine) per 5 mL, 100 mL**

omit from the column headed "Responsible Person": **FM** *substitute:* **AS**

[88] **Schedule 1, entry for Prednisolone in each of the forms: Suppositories 5 mg (as sodium phosphate), 10; and Enema, retention, 20 mg (as sodium phosphate) in 100 mL**

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[89] **Schedule 1, after entry for Primidone in the form Tablet 250 mg**

insert:

Tablet 250 mg (USP)	Oral	APO-Primidone	LM	MP NP	200	2	100

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

(a) *omit from the column headed "Circumstances":* **C9005 C9006 C9014 C9017 C9021 C9024 C9025 C9026 C9029** *substitute:* **C10018 C10037 C10038 C10044 C10054 C10057**

(b) *omit from the column headed "Purposes":* **P9005 P9014 P9017** *substitute:* **P10037 P10038**

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

(a) *omit from the column headed "Circumstances":* **C9005 C9006 C9014 C9017 C9021 C9024 C9025 C9026 C9029** *substitute:* **C10018 C10037 C10038 C10044 C10054 C10057**

(b) *omit from the column headed "Purposes":* **P9006 P9024 P9026** *substitute:* **P10044 P10054**

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

(a) *omit from the column headed "Circumstances":* **C9005 C9006 C9014 C9017 C9021 C9024 C9025 C9026 C9029** *substitute:* **C10018 C10037 C10038 C10044 C10054 C10057**

(b) *omit from the column headed "Purposes":* **P9021 P9025 P9029** *substitute:* **P10018 P10057**

[93] **Schedule 1, entry for Risperidone in the form Oral solution 1 mg per mL, 100 mL *[Maximum Quantity: 1; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* **C5993 C6897 C6938**

(b) *insert in numerical order in the column headed "Circumstances":* **C6898 C6899 C10020 C10021 C10052**

(c) *omit from the column headed "Purposes":* **P5993 P6897 P6938** *substitute:* **P6898 P6899 P10020 P10021 P10052**

[94] **Schedule 1, entry for Risperidone in the form Oral solution 1 mg per mL, 100 mL *[Maximum Quantity: 1; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C5993 C6897 C6938**

(b) *insert in numerical order in the column headed "Circumstances":* **C6898 C6899 C10020 C10021 C10052**

[95] **Schedule 1, entry for Risperidone in the form Tablet 0.5 mg *[Maximum Quantity: 60; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances" (all instances):* **C6010**

(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C10020 C10021 C10052**

(c) *omit from the column headed "Purposes" (all instances):* **P6010**

(d) *insert in numerical order in the column headed "Purposes" (all instances):* **P10020 P10021 P10052**

[96] **Schedule 1, entry for Risperidone in the form Tablet 0.5 mg *[Maximum Quantity: 60; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances" (all instances):* **C6010**

(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C10020 C10021 C10052**

[97] **Schedule 1, entry for Risperidone in the form Tablet 1 mg *[Maximum Quantity: 60; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances" (all instances):* **C5993 C6897 C6938**

(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C6898 C6899 C10020 C10021 C10052**

(c) *omit from the column headed "Purposes" (all instances):* **P5993 P6897 P6938** *substitute:* **P6898 P6899 P10020 P10021 P10052**

[98] **Schedule 1, entry for Risperidone in the form Tablet 1 mg *[Maximum Quantity: 60; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances" (all instances):* **C5993 C6897 C6938**

(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C6898 C6899 C10020 C10021 C10052**

[99] **Schedule 1, entry for Rituximab in the form Solution for I.V. infusion 100 mg in 10 mL**

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

	Truxima	EW	MP	C7399 C7400 C9451 C9542	See Note 3	See Note 3	2	PB(100)

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[100] Schedule 1, entry for Rituximab in the form Solution for I.V. infusion 500 mg in 50 mL

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

	Truxima	EW	MP	C7399 C7400 C9451 C9542	See Note 3	See Note 3	1	PB(100)

[101] Schedule 1, entry for Somatropin in the form Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative)

(a) *omit from the column headed "Circumstances":* **C9300 C9301**

(b) *insert in numerical order in the column headed "Circumstances":* **C10011 C10012 C10027 C10042**

[102] Schedule 1, entry for Somatropin in the form Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative)

(a) *omit from the column headed "Circumstances":* **C9300 C9301**

(b) *insert in numerical order in the column headed "Circumstances":* **C10011 C10012 C10027 C10042**

[103] Schedule 1, entry for Somatropin in the form Solution for injection 10 mg (30 i.u.) in 2 mL cartridge (with preservative)

(a) *omit from the column headed "Circumstances":* **C9300 C9301**

(b) *insert in numerical order in the column headed "Circumstances":* **C10011 C10012 C10027 C10042**

[104] Schedule 1, entry for Tamoxifen in the form Tablet 20 mg (as citrate)

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[105] Schedule 1, entry for Temazepam

(a) *omit from the column headed "Responsible Person" for the brand "Normison" (all instances):* **QA** *substitute:* **AS**

(b) *omit from the column headed "Responsible Person" for the brand "Temtabs" (all instances):* **FM** *substitute:* **LN**

[106] Schedule 1, entry for Temozolomide in the form Capsule 5 mg

omit from the column headed "Responsible Person" for the brand "Temizole 5" (all instances): **QA** *substitute:* **AS**

[107] Schedule 1, entry for Temozolomide in the form Capsule 20 mg

omit from the column headed "Responsible Person" for the brand "Temizole 20" (all instances): **QA** *substitute:* **AS**

[108] Schedule 1, entry for Temozolomide in the form Capsule 100 mg

omit from the column headed "Responsible Person" for the brand "Temizole 100" (all instances): **QA** *substitute:* **AS**

[109] Schedule 1, entry for Temozolomide in the form Capsule 140 mg

omit from the column headed "Responsible Person" for the brand "Temizole 140" (all instances): **QA** *substitute:* **AS**

[110] Schedule 1, entry for Temozolomide in the form Capsule 250 mg

omit from the column headed "Responsible Person" for the brand "Temizole 250": **QA** *substitute:* **AS**

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[111] Schedule 1, entry for Teriflunomide

(a) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

a	Pharmacor Teriflunomide	CR	MP	C6854 C7741	28	5	28	

(b) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

a	Teriflunomide GH	GQ	MP	C6854 C7741	28	5	28	

[112] Schedule 1, entry for Trametinib in the form Tablet 500 micrograms *[Maximum Quantity: 90; Number of Repeats: 3]*

(a) *omit from the column headed "Circumstances":* **C6778**

(b) *insert in numerical order in the column headed "Circumstances":* **C10051**

(c) *omit from the column headed "Purposes":* **P6778**

(d) *insert in numerical order in the column headed "Purposes":* **P10051**

[113] Schedule 1, entry for Trametinib in the form Tablet 500 micrograms *[Maximum Quantity: 90; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C6778**

(b) *insert in numerical order in the column headed "Circumstances":* **C10051**

[114] Schedule 1, entry for Trametinib in the form Tablet 2 mg *[Maximum Quantity: 30; Number of Repeats: 3]*

(a) *omit from the column headed "Circumstances":* **C6778**

(b) *insert in numerical order in the column headed "Circumstances":* **C10051**

(c) *omit from the column headed "Purposes":* **P6778**

(d) *insert in numerical order in the column headed "Purposes":* **P10051**

[115] Schedule 1, entry for Trametinib in the form Tablet 2 mg *[Maximum Quantity: 30; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C6778**

(b) *insert in numerical order in the column headed "Circumstances":* **C10051**

[116] Schedule 1, entry for Trastuzumab in the form Powder for I.V. infusion 150 mg

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

	Ontruzant	MK	MP	C9349 C9353 C9354 C9356 C9461 C9571 C9573 C9628	See Note 3	See Note 3	1	PB(100)

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[117] Schedule 1, entry for Triamcinolone in the form Cream containing triamcinolone acetonide 200 micrograms per g, 100 g

(a) *omit from the column headed "Responsible Person":* **QA** *substitute:* **AS**

(b) *omit from the column headed "Responsible Person":* **FM** *substitute:* **LN**

[118] Schedule 1, entry for Triamcinolone in the form Injection containing triamcinolone acetonide 10 mg in 1 mL

omit from the column headed "Responsible Person": **QA** *substitute:* **AS**

[119] Schedule 1, entry for Triamcinolone in the form Ointment containing triamcinolone acetonide 200 micrograms per g, 100 g

(a) *omit from the column headed "Responsible Person":* **QA** *substitute:* **AS**

(b) *omit from the column headed "Responsible Person":* **FM** *substitute:* **LN**

[120] Schedule 1, entry for Triamcinolone with neomycin, gramicidin and nystatin in the form Ear drops containing triamcinolone acetonide 0.9 mg with neomycin 2.25 mg (as sulfate), gramicidin 225 micrograms and nystatin 90,000 units per mL, 7.5 mL

(a) *omit from the column headed "Responsible Person":* **QA** *substitute:* **AS**

(b) *omit from the column headed "Responsible Person":* **FM** *substitute:* **LN**

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

(a) *omit from the column headed "Responsible Person":* **QA** *substitute:* **AS**

(b) *omit from the column headed "Responsible Person":* **FM** *substitute:* **LN**

[122] Schedule 1, entry for Ursodeoxycholic acid in each of the forms: Capsule 250 mg; and Tablet 500 mg

omit from the column headed "Responsible Person": **OA** *substitute:* **FD**

[123] Schedule 1, omit entry for Verteporfin

[124] Schedule 3, after details relevant to Responsible Person code FB

insert:

FD	Dr Falk Pharma Australia Pty Ltd	40 631 091 131

[125] Schedule 3

omit:

FM	Fawns and McAllan Proprietary Limited	16 004 296 066

[126] Schedule 3

omit:

OA	Orphan Australia Pty Ltd	11 067 189 342

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[127] Schedule 4, Part 1, after entry for Abatacept

insert:

Abemaciclib	C10019			Locally advanced or metastatic breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop disease progression while receiving treatment with this drug for this condition; AND Patient must have stable or responding disease; AND The treatment must be in combination with anastrozole or letrozole; AND The treatment must not be in combination with palbociclib or ribociclib. Patient must not be premenopausal. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.	Compliance with Authority Required procedures
	C10032			Locally advanced or metastatic breast cancer Initial treatment Patient must not have previously been treated with an aromatase inhibitor for advanced or metastatic breast cancer; AND Patient must not have previously been treated with palbociclib or ribociclib; OR Patient must have developed an intolerance to palbociclib or ribociclib of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND The treatment must be in combination with anastrozole or letrozole; AND The treatment must not be in combination with palbociclib or ribociclib. Patient must not be premenopausal.	Compliance with Authority Required procedures

[128] Schedule 4, Part 1, entry for Avelumab

(a) *omit:*

	C8856			Stage IV (metastatic) Merkel Cell Carcinoma Continuing treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND 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 exceed a total of 12 doses at a maximum dose of 10 mg per kg every 2 weeks under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 8856

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

	C10023			Stage IV (metastatic) Merkel Cell Carcinoma Continuing treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND 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 exceed a maximum dose of 10 mg per kg every 2 weeks under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 10023

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[129] Schedule 4, Part 1, entry for Cobimetinib

(a) *omit:*

	C6839	P6839		Unresectable Stage III or Stage IV malignant melanoma Initial treatment Patient must be receiving PBS subsidised vemurafenib concomitantly for this condition; AND Patient must not have progressive disease when treated with a BRAF inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 6839

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

	C10033	P10033		Unresectable Stage III or Stage IV malignant melanoma Initial treatment Patient must be receiving PBS subsidised vemurafenib concomitantly for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 10033

[130] Schedule 4, Part 1, entry for Imatinib

(a) *omit:*

	C6510	P6510		Chronic Myeloid Leukaemia (CML) Initial treatment Patient must have a primary diagnosis of chronic myeloid leukaemia; AND The condition must be in the accelerated phase; AND The condition must be expressing the Philadelphia chromosome; OR The condition must have the transcript BCR-ABL tyrosine kinase. Accelerated phase is defined by the presence of 1 or more of the following: 1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or 2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or 3. Peripheral basophils greater than or equal to 20%; or 4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or 5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome). Applications for authorisation must be in writing and must include: (a) a completed authority prescription form; and (b) a completed Imatinib Mesilate PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and (c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criteria (1), (2), (3) and (5) above, or details of the dates of assessments in the case of progressive splenomegaly	Compliance with Written Authority Required procedures
	C6526	P6526		Chronic Myeloid Leukaemia (CML) Initial treatment Patient must a primary diagnosis of chronic myeloid leukaemia; AND The condition must be in the blast phase; AND The condition must be expressing the Philadelphia chromosome; OR The condition must have the transcript BCR-ABL tyrosine kinase. Blast crisis is defined as either:	Compliance with Written Authority Required procedures

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				1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or 2. Extramedullary involvement other than spleen and liver. Applications for authorisation must be in writing and must include: (a) a completed authority prescription form; and (b) a completed Imatinib Mesilate PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and (c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criterion (1) above, or details of the date of assessment in the case of extramedullary involvement	
	C6538	P6538		Chronic Myeloid Leukaemia (CML) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The condition must be in the accelerated phase; AND The condition must be expressing the Philadelphia chromosome; OR The condition must have the transcript BCR-ABL tyrosine kinase.	Compliance with Authority Required procedures
	C6557	P6557		Chronic Myeloid Leukaemia (CML) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The condition must be in the blast phase; AND The condition must be expressing the Philadelphia chromosome; OR The condition must have the transcript BCR-ABL tyrosine kinase.	Compliance with Authority Required procedures

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

	C10010	P10010		Chronic Myeloid Leukaemia (CML) Initial treatment Patient must have a primary diagnosis of chronic myeloid leukaemia; AND The condition must be in the accelerated phase; AND The condition must be expressing the Philadelphia chromosome; OR The condition must have the transcript BCR-ABL tyrosine kinase. Accelerated phase is defined by the presence of 1 or more of the following: 1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or 2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or 3. Peripheral basophils greater than or equal to 20%; or 4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or 5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).	Compliance with Authority Required procedures
	C10026	P10026		Chronic Myeloid Leukaemia (CML) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The condition must be in the accelerated phase; AND The condition must be expressing the Philadelphia chromosome; OR The condition must have the transcript BCR-ABL tyrosine kinase.	Compliance with Authority Required procedures - Streamlined Authority Code 10026
	C10035	P10035		Chronic Myeloid Leukaemia (CML) Initial treatment Patient must a primary diagnosis of chronic myeloid leukaemia; AND	Compliance with Authority Required

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				The condition must be in the blast phase; AND The condition must be expressing the Philadelphia chromosome; OR The condition must have the transcript BCR-ABL tyrosine kinase. Blast crisis is defined as either: 1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or 2. Extramedullary involvement other than spleen and liver.	procedures
	C10048	P10048		Chronic Myeloid Leukaemia (CML) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The condition must be in the blast phase; AND The condition must be expressing the Philadelphia chromosome; OR The condition must have the transcript BCR-ABL tyrosine kinase.	Compliance with Authority Required procedures - Streamlined Authority Code 10048

[131] Schedule 4, Part 1, entry for Palbociclib

substitute:

Palbociclib	C10013			Locally advanced or metastatic breast cancer Initial treatment - Grandfather patients Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 May 2019; AND Patient must not have previously been treated with an aromatase inhibitor prior to initiating treatment with this drug for this condition; AND Patient must not have previously been treated with abemaciclib or ribociclib; OR Patient must have developed an intolerance to abemaciclib or ribociclib of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less prior to initiating 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 Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND The treatment must be in combination with anastrozole or letrozole; AND The treatment must not be in combination with abemaciclib or ribociclib. Patient must not be premenopausal. 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.	Compliance with Authority Required procedures
	C10015			Locally advanced or metastatic breast cancer Initial treatment Patient must not have previously been treated with an aromatase inhibitor for advanced or metastatic breast cancer; AND Patient must not have previously been treated with abemaciclib or ribociclib; OR Patient must have developed an intolerance to abemaciclib or ribociclib of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND	Compliance with Authority Required procedures

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				The treatment must be in combination with anastrozole or letrozole; AND The treatment must not be in combination with abemaciclib or ribociclib. Patient must not be premenopausal.	
	C10043			Locally advanced or metastatic breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop disease progression while receiving treatment with this drug for this condition; AND Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND The treatment must be in combination with anastrozole or letrozole; AND The treatment must not be in combination with abemaciclib or ribociclib. Patient must not be premenopausal. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.	Compliance with Authority Required procedures

[132] Schedule 4, Part 1, entry for Ribociclib

substitute:

Ribociclib	C10018	P10018		Locally advanced or metastatic breast cancer Initial treatment Patient must not have previously been treated with an aromatase inhibitor for advanced or metastatic breast cancer; AND Patient must not have previously been treated with abemaciclib or palbociclib; OR Patient must have developed an intolerance to abemaciclib or palbociclib of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND The treatment must be in combination with anastrozole or letrozole; AND The treatment must not be in combination with abemaciclib or palbociclib. Patient must not be premenopausal.	Compliance with Authority Required procedures
	C10037	P10037		Locally advanced or metastatic breast cancer Initial treatment Patient must not have previously been treated with an aromatase inhibitor for advanced or metastatic breast cancer; AND Patient must not have previously been treated with abemaciclib or palbociclib; OR Patient must have developed an intolerance to abemaciclib or palbociclib of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND The treatment must be in combination with anastrozole or letrozole; AND The treatment must not be in combination with abemaciclib or palbociclib; AND Patient must require dosage reduction requiring a pack of 21 tablets. Patient must not be premenopausal.	Compliance with Authority Required procedures

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	C10038	P10038		Locally advanced or metastatic breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop disease progression while receiving treatment with this drug for this condition; AND Patient must have stable or responding disease; AND The treatment must be in combination with anastrozole or letrozole; AND The treatment must not be in combination with abemaciclib or palbociclib; AND Patient must require dosage reduction requiring a pack of 21 tablets. Patient must not be premenopausal. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.	Compliance with Authority Required procedures
	C10044	P10044		Locally advanced or metastatic breast cancer Initial treatment Patient must not have previously been treated with an aromatase inhibitor for advanced or metastatic breast cancer; AND Patient must not have previously been treated with abemaciclib or palbociclib; OR Patient must have developed an intolerance to abemaciclib or palbociclib of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND The treatment must be in combination with anastrozole or letrozole; AND The treatment must not be in combination with abemaciclib or palbociclib; AND Patient must require dosage reduction requiring a pack of 42 tablets. Patient must not be premenopausal.	Compliance with Authority Required procedures
	C10054	P10054		Locally advanced or metastatic breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop disease progression while receiving treatment with this drug for this condition; AND Patient must have stable or responding disease; AND The treatment must be in combination with anastrozole or letrozole; AND The treatment must not be in combination with abemaciclib or palbociclib; AND Patient must require dosage reduction requiring a pack of 42 tablets. Patient must not be premenopausal. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.	Compliance with Authority Required procedures
	C10057	P10057		Locally advanced or metastatic breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop disease progression while receiving treatment with this drug for this condition; AND Patient must have stable or responding disease; AND The treatment must be in combination with anastrozole or letrozole; AND The treatment must not be in combination with abemaciclib or palbociclib. Patient must not be premenopausal. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.	Compliance with Authority Required procedures

[133] Schedule 4, Part 1, entry for Risperidone

(a) *omit:*

	C5993	P5993		Behavioural disturbances The condition must be characterised by psychotic symptoms and aggression; AND Patient must have dementia of the Alzheimer type; AND Patient must have failed to respond to non-pharmacological methods of treatment; AND The treatment must be limited to a maximum duration of 12 weeks.	Compliance with Authority Required procedures - Streamlined Authority Code 5993
	C6010	P6010		Behavioural disturbances The condition must be characterised by psychotic symptoms and aggression; AND Patient must have dementia of the Alzheimer type; AND Patient must have failed to respond to non-pharmacological methods of treatment; AND The treatment must be limited to a maximum duration of 12 weeks.	Compliance with Authority Required procedures - Streamlined Authority Code 6010

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

	C10020	P10020		Behavioural disturbances Initial treatment The condition must be characterised by psychotic symptoms and aggression; AND Patient must have dementia of the Alzheimer type; AND Patient must have failed to respond to non-pharmacological methods of treatment; AND Patient must not receive more than 12 weeks of treatment under this restriction. A patient may only qualify for 12 weeks of PBS-subsidised treatment under this restriction once in a 12 month period.	Compliance with Authority Required procedures - Streamlined Authority Code 10020
	C10021	P10021		Behavioural disturbances Continuing treatment, trial of dose reduction or cessation of treatment The condition must be characterised by psychotic symptoms and aggression; AND Patient must have dementia of the Alzheimer type; AND Patient must have responded to an initial course of treatment with this drug for this condition; AND Patient must have failed to respond to non-pharmacological methods of treatment; AND The treatment must be for dose tapering purposes as part of a trial of treatment reduction or cessation; OR Patient must have trialled a period of treatment reduction or cessation with this drug for this condition and experienced worsening or re-emergence of symptoms during this trial, and retrials are considered periodically; AND Patient must be optimised on non-pharmacological methods of treatment. The patient's response to treatment and a trial of treatment reduction or cessation must be discussed formally with a psychiatrist or geriatrician or in a documented clinical review process involving a least one other medical practitioner, or be reviewed by a psychiatrist or geriatrician. Response to treatment is defined as a significant reduction in symptoms of psychosis or aggression. Patients must cease treatment if there is no improvement in symptoms of psychosis and aggression, or worsening of symptoms with therapy. Patients must be monitored for adverse effects such as falls, drowsiness leading to reduced self-care, incontinence, reduced nutrition, reduced ability to communicate needs/wishes and take part in activities. Therapy must be ceased if harms of therapy outweigh benefits. Trials of reduction or cessation of therapy should be considered periodically with the intention of maintaining symptom control through non-pharmacological measures wherever possible and/or lowest effective dose therapy. Evidence of patient benefit from therapy, failure of non-pharmacological approaches to manage symptoms in the absence of therapy, and recurrence of symptoms following reduction or cessation of therapy, trialled on at least 1 occasion, must be documented in the patient's medical records.	Compliance with Authority Required procedures

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	C10052	P10052		Behavioural disturbances Grandfather treatment for the trial of dose reduction or cessation of treatment in a patient prescribed risperidone prior to 1 January 2020 The condition must be characterised by psychotic symptoms and aggression; AND Patient must have dementia of the Alzheimer type; AND Patient must have received PBS-subsidised treatment with this drug for this condition prior to 1 January 2020; AND Patient must have responded to PBS-subsidised treatment with this drug for this condition; AND Patient must have failed to respond to non-pharmacological methods of treatment; AND Patient must be optimised on non-pharmacological methods of treatment; AND The treatment must be for dose tapering purposes as part of a trial of treatment reduction or cessation; OR Patient must have trialled a period of treatment reduction or cessation with this drug for this condition and experienced worsening or re-emergence of symptoms during this trial, and retrials are considered periodically; AND Patient must not receive more than 12 weeks of treatment under this restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime. The patient's response to treatment and a trial of treatment reduction or cessation must be discussed formally with a psychiatrist or geriatrician or in a documented clinical review process involving a least one other medical practitioner, or be reviewed by a psychiatrist or geriatrician. Response to treatment is defined as a significant reduction in symptoms of psychosis or aggression. Patients must cease treatment if there is no improvement in symptoms of psychosis and aggression, or worsening of symptoms with therapy. Patients must be monitored for adverse effects such as falls, drowsiness leading to reduced self-care, incontinence, reduced nutrition, reduced ability to communicate needs/wishes and take part in activities. Therapy must be ceased if harms of therapy outweigh benefits. Trials of reduction or cessation of therapy should be considered periodically with the intention of maintaining symptom control through non-pharmacological measures wherever possible and/or lowest effective dose therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 10052

[134] Schedule 4, Part 1, entry for Somatropin

(a) *omit:*

	C9300			Severe growth hormone deficiency Initial treatment Must be treated by an endocrinologist. Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause; OR Patient must have adult onset growth hormone deficiency secondary to organic hypothalamic or pituitary disease; AND Patient must have an insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; OR Patient must have an arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; OR Patient must have a glucagon provocation test with maximum serum GH less than 3 micrograms per litre. Patient must be aged 18 years or older. Grandfathered patient who has previously received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2018 must have met all the initial restriction criteria prior to initiating non-PBS subsidised treatment. Additional information of a baseline serum IGF-1 measurement, including the date of testing and laboratory reference range for age and sex, of less than 12 weeks prior to initiating non-PBS subsidised treatment with this drug for this condition must be provided at the time of application. A Grandfathered 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. The authority application must be in writing and must include: A completed authority prescription form; AND A completed Severe Growth Hormone Deficiency supporting information form; AND	Compliance with Written Authority Required procedures

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				Confirmation of childhood onset growth hormone deficiency due to a congenital, genetic or structural cause; OR Confirmation of adult onset growth hormone deficiency due to organic hypothalamic or pituitary disease; AND Results of the growth hormone stimulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender; AND A baseline serum IGF-1 measurement, including the date of testing and laboratory reference range for age and sex, of less than 12 weeks old at the time of application.	
	C9301			Severe growth hormone deficiency Continuing treatment Must be treated by an endocrinologist or in consultation with an endocrinologist. Patient must have previously received PBS-subsidised therapy with this drug for this condition at the age of 18 years or older; AND Patient must maintain IGF-1 levels within the normal range for age and sex. Patient must be aged 18 years or older. The authority application must be in writing and must include: A completed authority prescription form; AND A completed Severe Growth Hormone Deficiency supporting information form; AND A serum IGF-1 measurement, including the date of testing and laboratory reference range for age and sex, of less than 12 weeks old at the time of application.	Compliance with Written Authority Required procedures

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

	C10011			Severe growth hormone deficiency Initial treatment of childhood onset growth hormone deficiency in a patient who has received non-PBS subsidised treatment as a child Must be treated by an endocrinologist. Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause; AND Patient must have previously received non-PBS subsidised treatment with this drug for this condition as a child; AND Patient must have current or historical evidence of an insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; OR Patient must have current or historical evidence of an arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; OR Patient must have current or historical evidence of a glucagon provocation test with maximum serum GH less than 3 micrograms per litre. Patient must have a mature skeleton. The authority application must be in writing and must include: A completed authority prescription form; AND A completed Severe Growth Hormone Deficiency supporting information form; AND Results of the growth hormone stimulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender; AND A serum IGF-1 measurement, including the date of testing and laboratory reference range for age and sex, of less than 12 weeks old at the time of application.	Compliance with Written Authority Required procedures
	C10012			Severe growth hormone deficiency Continuing treatment in adults Must be treated by an endocrinologist or in consultation with an endocrinologist. Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause; OR Patient must have adult onset growth hormone deficiency secondary to organic hypothalamic or pituitary disease; AND	Compliance with Written Authority Required procedures

				Patient must maintain IGF-1 levels within the normal range for age and sex. The authority application must be in writing and must include: A completed authority prescription form; AND A completed Severe Growth Hormone Deficiency supporting information form; AND A serum IGF-1 measurement, including the date of testing and laboratory reference range for age and sex, of less than 12 weeks old at the time of application.	
	C10027			Severe growth hormone deficiency Initial treatment of childhood onset growth hormone deficiency in a patient who has received PBS-subsidised treatment as a child Must be treated by an endocrinologist. Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition as a child. Patient must have a mature skeleton. The authority application must be in writing and must include: A completed authority prescription form; AND A completed Severe Growth Hormone Deficiency supporting information form; AND A serum IGF-1 measurement, including the date of testing and laboratory reference range for age and sex, of less than 12 weeks old at the time of application.	Compliance with Written Authority Required procedures
	C10042			Severe growth hormone deficiency Initial treatment of adult onset growth hormone deficiency Must be treated by an endocrinologist. Patient must have adult onset growth hormone deficiency secondary to organic hypothalamic or pituitary disease; AND Patient must have an insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; OR Patient must have an arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; OR Patient must have a glucagon provocation test with maximum serum GH less than 3 micrograms per litre. Patient must be aged 18 years or older. Grandfathered patient who has previously received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2018 must have met all the initial restriction criteria prior to initiating non-PBS subsidised treatment. Additional information of a baseline serum IGF-1 measurement, including the date of testing and laboratory reference range for age and sex, of less than 12 weeks prior to initiating non-PBS subsidised treatment with this drug for this condition must be provided at the time of application. A Grandfathered 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. The authority application must be in writing and must include: A completed authority prescription form; AND A completed Severe Growth Hormone Deficiency supporting information form; AND Results of the growth hormone stimulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender; AND A baseline serum IGF-1 measurement, including the date of testing and laboratory reference range for age and sex, of less than 12 weeks old prior to initiating treatment.	Compliance with Written Authority Required procedures

[135] Schedule 4, Part 1, entry for Trametinib

(a) *omit:*

	C6778	P6778		Unresectable Stage III or Stage IV malignant melanoma Initial treatment Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition; AND	Compliance with Authority Required procedures -

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				Patient must not have had progressive disease when treated with a BRAF inhibitor.	Streamlined Authority Code 6778

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

	C10051	P10051		Unresectable Stage III or Stage IV malignant melanoma Initial treatment Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 10051

[136] Schedule 4, Part 1, omit entry for Verteporfin

[137] Schedule 5, entry for Abacavir with lamivudine in the form Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg *[GRP-21981]*

omit from the column headed "Brand": **Abacavir/Lamivudine 600/300 APOTEX**

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