PB 63 of 2018

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2018 (No. 8)

National Health Act 1953

I, LISA LA RANCE, 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 27 JULY 2018

LISA LA RANCE
Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health

1 Name of Instrument

(1) This Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2018 (No. 8)*.

(2) This Instrument may also be cited as PB 63 of 2018.

2 Commencement

This Instrument commences on 1 August 2018.

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 Aciclovir in the form Tablet 200 mg *[Maximum Quantity: 50; Number of Repeats: 0]*

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

	a	APO-Aciclovir	TX	MP NP	C5936 C5942	P5936	50	0	50

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

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

	a	APO-Aciclovir	TX	MP NP	C5936 C5942	P5942	90	5	90

[3] Schedule 1, entry for Aciclovir in the form Tablet 800 mg

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

	a	APO-Aciclovir	TX	MP NP	C5959 C5967		35	0	35

[4] Schedule 1, entry for Aclidinium with formoterol

omit from the column headed "Circumstances": **C5763** *substitute:* **C7798**

[5] Schedule 1, entry for Amlodipine with atorvastatin in the form Tablet 5 mg amlodipine (as besilate) with 10 mg atorvastatin (as calcium)

omit:

	a	APO-Amlodipine/Atorvastatin 5/10	TX	MP NP			30	5	30

[6] Schedule 1, entry for Amlodipine with atorvastatin in the form Tablet 5 mg amlodipine (as besilate) with 20 mg atorvastatin (as calcium)

omit:

	a	APO-Amlodipine/Atorvastatin 5/20	TX	MP NP			30	5	30

[7] Schedule 1, entry for Amlodipine with atorvastatin in the form Tablet 5 mg amlodipine (as besilate) with 40 mg atorvastatin (as calcium)

omit:

	a	APO-Amlodipine/Atorvastatin 5/40	TX	MP NP			30	5	30

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[8] **Schedule 1, entry for Amlodipine with atorvastatin in the form Tablet 5 mg amlodipine (as besilate) with 80 mg atorvastatin (as calcium)**

omit:

a	APO-Amlodipine/Atorvastatin 5/80	TX	MP NP		30	5	30

[9] **Schedule 1, entry for Amlodipine with atorvastatin in the form Tablet 10 mg amlodipine (as besilate) with 10 mg atorvastatin (as calcium)**

omit:

a	APO-Amlodipine/Atorvastatin 10/10	TX	MP NP		30	5	30

[10] **Schedule 1, entry for Amlodipine with atorvastatin in the form Tablet 10 mg amlodipine (as besilate) with 20 mg atorvastatin (as calcium)**

omit:

a	APO-Amlodipine/Atorvastatin 10/20	TX	MP NP		30	5	30

[11] **Schedule 1, entry for Amlodipine with atorvastatin in the form Tablet 10 mg amlodipine (as besilate) with 40 mg atorvastatin (as calcium)**

omit:

a	APO-Amlodipine/Atorvastatin 10/40	TX	MP NP		30	5	30

[12] **Schedule 1, entry for Amlodipine with atorvastatin in the form Tablet 10 mg amlodipine (as besilate) with 80 mg atorvastatin (as calcium)**

omit:

a	APO-Amlodipine/Atorvastatin 10/80	TX	MP NP		30	5	30

[13] **Schedule 1, entry for Amoxicillin with clavulanic acid in the form Powder for oral suspension containing 125 mg amoxicillin (as trihydrate) with 31.25 mg clavulanic acid (as potassium clavulanate) per 5 mL, 75 mL *[Maximum Quantity: 1; Number of Repeats: 0]***

(a) *omit:*

a	APO-Amoxycillin and Clavulanic Acid 125/31.25	TX	PDP	C5833 C5894	1	0	1

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(b) *omit from the column headed "Schedule Equivalent" for the brand "Curam":* **a**

[14] Schedule 1, entry for Amoxicillin with clavulanic acid in the form Powder for oral suspension containing 125 mg amoxicillin (as trihydrate) with 31.25 mg clavulanic acid (as potassium clavulanate) per 5 mL, 75 mL *[Maximum Quantity: 1; Number of Repeats: 1]*

(a) *omit:*

	a	APO-Amoxycillin and Clavulanic Acid 125/31.25	TX	MP NP	C5832 C5893	1	1	1

(b) *omit from the column headed "Schedule Equivalent" for the brand "Curam":* **a**

(c) *omit from the column headed "Brand" for the brand "Curam":* **Curam**

(d) *omit from the column headed "Responsible Person" for the brand "Curam":* **SZ**

[15] Schedule 1, entry for Amoxicillin with clavulanic acid in the form Powder for oral suspension containing 400 mg amoxicillin (as trihydrate) with 57 mg clavulanic acid (as potassium clavulanate) per 5 mL, 60 mL *[Maximum Quantity:1; Number of Repeats: 0]*

omit:

	a	APO-Amoxycillin and Clavulanic Acid 400/57	TX	PDP	C5833 C5894	1	0	1

[16] Schedule 1, entry for Amoxicillin with clavulanic acid in the form Powder for oral suspension containing 400 mg amoxicillin (as trihydrate) with 57 mg clavulanic acid (as potassium clavulanate) per 5 mL, 60 mL *[Maximum Quantity: 1; Number of Repeats: 1]*

omit:

	a	APO-Amoxycillin and Clavulanic Acid 400/57	TX	MP NP	C5832 C5893	1	1	1

[17] Schedule 1, entry for Apomorphine in all forms

insert in the column headed "Form" after the word "hydrochloride": **hemihydrate**

[18] Schedule 1, entry for Atropine in all forms

insert in the column headed "Form" after the word "sulfate": **monohydrate**

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[19] Schedule 1, entry for Baclofen in the form Intrathecal injection 10 mg in 5 mL

(a) *omit:*

	a	Bacthecal	DZ	MP	C6911 C6912 C6925 C6929 C6930 C6935 C6939 C6940	10	0	1	PB(100)

(b) *substitute:*

	a	Bacthecal	DZ	MP	C6911 C6912 C6925 C6929 C6930 C6935 C6939 C6940	10	0	1	PB(100)
				MP	C6911 C6912 C6925 C6929 C6930 C6935 C6939 C6940	10	0	5	PB(100)

[20] Schedule 1, entry for Cefalexin in the form Capsule 500 mg (as monohydrate)

(a) *omit:*

	a	Rancef	RA	PDP		20	0	20	

(b) *omit:*

	a	Rancef	RA	MP NP MW		20	1	20	

(c) *omit:*

	a	Rancef	RA	MP	P6188	40 CN6188	1 CN6188	20	

[21] Schedule 1, entry for Clopidogrel in the form Tablet 75 mg (as hydrogen sulfate)

insert in numerical order in the column headed "Circumstances" for the brand "Clopidogrel Sandoz": **C4165 C4166**

[22] Schedule 1, entry for Clozapine in the form Oral liquid 50 mg per mL, 100 mL

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

		Versacloz	PF	MP	C4998 C5001 C5015	1	0	1	D(100)

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

insert in the column headed "Form" after the word "phosphate": **hemihydrate**

[24] **Schedule 1, entry for Codeine with paracetamol**

insert in the column headed "Form" after the word "phosphate": **hemihydrate**

[25] **Schedule 1, entry for Cyclophosphamide for the form Tablet 50 mg**

insert in the column headed "Form" after the word "mg": **(anhydrous)**

[26] **Schedule 1, entry for Dantrolene in all forms**

insert in the column headed "Form" after the word "sodium": **hemiheptahydrate**

[27] **Schedule 1, entry for Diphenoxylate with atropine**

insert in the column headed "Form" after the word "sulfate": **monohydrate**

[28] **Schedule 1, entry for Diphtheria and tetanus vaccine, adsorbed, diluted for adult use**

omit:

	Injection 0.5 mL	Injection	MassBiologics tetanus and diphtheria toxoids adsorbed	CS	MP NP		10	0	10

[29] **Schedule 1, entry for Donepezil in the form Tablet containing donepezil hydrochloride 10 mg**

omit:

		a	Donepezil RBX	RA	MP NP	C4219 C4220 C4224	28	5	28

[30] **Schedule 1, entry for Doxycycline in the form Capsule 50 mg (as hydrochloride) (containing enteric coated pellets)**

omit from the column headed "Form": **hydrochloride** *substitute:* **hyclate**

[31] **Schedule 1, entry for Doxycycline in the form Capsule 100 mg (as hydrochloride) (containing enteric coated pellets)**

omit from the column headed "Form": **hydrochloride** *substitute:* **hyclate**

[32] **Schedule 1, entry for Doxycycline in the form Tablet 50 mg (as hydrochloride)**

omit from the column headed "Form": **hydrochloride** *substitute:* **hyclate**

[33] **Schedule 1, entry for Doxycycline in the form Tablet 100 mg (as hydrochloride)**

omit from the column headed "Form": **hydrochloride** *substitute:* **hyclate**

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[34] **Schedule 1, entry for Electrolyte replacement, oral in the form Oral rehydration salts containing glucose monohydrate 3.56 g, sodium chloride 470 mg, potassium chloride 300 mg and sodium acid citrate 530 mg per sachet, 10** ***[Maximum Quantity: 1; Number of Repeats: 0]***

(a) *insert in the column headed "Form" after the word "glucose":* **monohydrate**

(b) *omit:*

			a	Repalyte New Formulation	SW	MP	C5889 C6786	P5889	1	0	1
						NP	C5889		1	0	1

[35] **Schedule 1, entry for Electrolyte replacement, oral in the form Oral rehydration salts containing glucose monohydrate 3.56 g, sodium chloride 470 mg, potassium chloride 300 mg and sodium acid citrate 530 mg per sachet, 10** ***[Maximum Quantity: 30; Number of Repeats: 0]***

(a) *omit:*

			a	Repalyte New Formulation	SW	MP	C5889 C6786	P6786	30	0	1

(b) *omit from the column headed "Schedule Equivalent" for the brand "restore O.R.S.":* **a**

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

substitute:

Ezetimibe	Tablet 10 mg	Oral	a	APO-Ezetimibe	TX	MP NP	C5537 C5538 C5543 C5544 C5562 C5563 C5575 C5576 C5577 C5586 C5594	30	5	30
			a	Blooms The Chemist Ezetimibe	IB	MP NP	C5537 C5538 C5543 C5544 C5562 C5563 C5575 C5576 C5577 C5586 C5594	30	5	30
			a	EZEMICHOL	RW	MP NP	C5537 C5538 C5543 C5544 C5562 C5563 C5575 C5576 C5577 C5586 C5594	30	5	30
			a	Ezetimibe GH	GQ	MP NP	C5537 C5538 C5543 C5544 C5562 C5575	30	5	30

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							C5576 C5577 C5586 C5594			
			a	Ezetimibe Sandoz	SZ	MP NP	C5537 C5538 C5543 C5544 C5562 C5575 C5576 C5577 C5586 C5594	30	5	30
			a	Ezetrol	MK	MP NP	C5537 C5538 C5543 C5544 C5562 C5563 C5575 C5576 C5577 C5586 C5594	30	5	30
			a	Pharmacor Ezetimibe 10	CR	MP NP	C5537 C5538 C5543 C5544 C5562 C5563 C5575 C5576 C5577 C5586 C5594	30	5	30
			a	Zient 10mg	AF	MP NP	C5537 C5538 C5543 C5544 C5562 C5563 C5575 C5576 C5577 C5586 C5594	30	5	30

[37] Schedule 1, entry for Ezetimibe with simvastatin

substitute:

Ezetimibe with simvastatin	Tablet 10 mg-10 mg	Oral	a	APO-Ezetimibe/Simvastatin 10/10	TX	MP NP	C4068 C4069 C4085 C4086 C4096 C4097 C4120 C4121 C4147	30	5	30
			a	EZETIMIBE/SIMVASTATIN SANDOZ	SZ	MP NP	C4068 C4069 C4085 C4086 C4096 C4097 C4120 C4121 C4147	30	5	30
			a	Vytorin	MK	MP NP	C4068 C4069 C4085 C4086 C4096 C4097 C4120 C4121 C4147	30	5	30

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		a	Zeklen 10/10 mg	AF	MP NP	C4068 C4069 C4085 C4086 C4096 C4097 C4120 C4121 C4147	30	5	30
Tablet 10 mg-20 mg	Oral	a	APO-Ezetimibe/Simvastatin 10/20	TX	MP NP	C4068 C4069 C4085 C4086 C4096 C4097 C4120 C4121 C4147	30	5	30
		a	EZETIMIBE/SIMVASTATIN SANDOZ	SZ	MP NP	C4068 C4069 C4085 C4086 C4096 C4097 C4120 C4121 C4147	30	5	30
		a	Vytorin	MK	MP NP	C4068 C4069 C4085 C4086 C4096 C4097 C4120 C4121 C4147	30	5	30
		a	Zeklen 10/20 mg	AF	MP NP	C4068 C4069 C4085 C4086 C4096 C4097 C4120 C4121 C4147	30	5	30
Tablet 10 mg-40 mg	Oral	a	APO-Ezetimibe/Simvastatin 10/40	TX	MP NP	C4068 C4069 C4085 C4086 C4096 C4097 C4120 C4121	30	5	30
		a	EZETIMIBE/SIMVASTATIN SANDOZ	SZ	MP NP	C4068 C4069 C4085 C4086 C4096 C4097 C4120 C4121	30	5	30
		a	Vytorin	MK	MP NP	C4068 C4069 C4085 C4086 C4096 C4097 C4120 C4121	30	5	30
		a	Zeklen 10/40 mg	AF	MP NP	C4068 C4069 C4085 C4086 C4096 C4097 C4120 C4121	30	5	30
Tablet 10 mg-80 mg	Oral	a	APO-Ezetimibe/Simvast	TX	MP NP	C4068 C4069 C4085 C4086	30	5	30

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		atin 10/80			C4096 C4097 C4120 C4121					
	a	EZETIMIBE/SIMVASTATIN SANDOZ	SZ	MP NP	C4068 C4069 C4085 C4086 C4096 C4097 C4120 C4121	30	5	30		
	a	Vytorin	MK	MP NP	C4068 C4069 C4085 C4086 C4096 C4097 C4120 C4121	30	5	30		
	a	Zeklen 10/80 mg	AF	MP NP	C4068 C4069 C4085 C4086 C4096 C4097 C4120 C4121	30	5	30		

[38] Schedule 1, entry for Ferrous sulfate

omit from the column headed "Form": **Oral liquid 30 mg per mL, 250 mL**

substitute: **Oral liquid containing 30 mg ferrous sulfate heptahydrate per mL, 250 mL**

[39] Schedule 1, entry for Flucloxacillin in all forms

insert in the column headed "Form", in the brackets after the word "sodium": **monohydrate**

[40] Schedule 1, entry for Fluconazole in the form Capsule 200 mg

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

			a	Fluconazole APOTEX	GX	MP NP	C5978 C5989 C5996 C6002 C6023 C6030	28	5	28	

[41] Schedule 1, after entry for Follitropin beta in the form Solution for injection 900 I.U. in 1.08 mL multi-dose cartridge

insert:

Follitropin delta	Injection 12 micrograms in 0.36 mL pre-filled multi-dose pen	Injection		Rekovelle	FP	MP	C5027	5	0	1	D(100)
	Injection 36 micrograms in 1.08 mL pre-filled multi-dose pen	Injection		Rekovelle	FP	MP	C5027	5	0	1	D(100)
	Injection 72 micrograms in 2.16 mL pre-filled multi-dose pen	Injection		Rekovelle	FP	MP	C5027	4	0	1	D(100)

[42] **Schedule 1, entry for Furosemide in the form Injection 20 mg in 2 mL**

omit from the column headed "Responsible Person" for the brand "Frusemide-Claris": **AE** *substitute:* **BX**

[43] **Schedule 1, entry for Gabapentin in the form Capsule 300 mg**

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

			a	Gabapentin generichealth	HQ	MP NP	C4928		100	5	100

(b) *omit:*

			a	Gabapentin GH	GQ	MP NP	C4928		100	5	100

[44] **Schedule 1, entry for Gabapentin in the form Capsule 400 mg**

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

			a	Gabapentin generichealth	HQ	MP NP	C4928		100	5	100

(b) *omit:*

			a	Gabapentin GH	GQ	MP NP	C4928		100	5	100

[45] **Schedule 1, after entry for Glatiramer in the form Injection containing glatiramer acetate 40 mg in 1 mL single dose pre-filled syringe**

insert:

Glecaprevir with pibrentasvir	Tablet containing 100 mg glecaprevir with 40 mg pibrentasvir	Oral		Maviret	VE	MP NP	C7593 C7594 C7615	P7593	84	1	84
						MP NP	C7593 C7594 C7615	P7615	84	2	84
						MP NP	C7593 C7594 C7615	P7594	84	3	84

[46] **Schedule 1, entry for Golimumab in the form Injection 100 mg in 1 mL single use pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C7662**

(b) *omit from the column headed "Circumstances":* **C7675**

(c) *insert in numerical order for the column headed "Circumstances":* **C7827 C7853**

(d) *omit from the column headed "Purposes":* **P7662 P7675**

(e) *insert in numerical order in the column headed "Purposes":* **P7827 P7853**

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(f) *omit from the column headed "Number of Repeats":* **1** *substitute:* **4**

[47] Schedule 1, entry for Golimumab in the form Injection 100 mg in 1 mL single use pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C7662**

(b) *omit from the column headed "Circumstances":* **C7675**

(c) *insert in numerical order in the column headed "Circumstances":* **C7827 C7853**

[48] Schedule 1, entry for Ibrutinib

substitute:

Ibrutinib	Capsule 140 mg	Oral	Imbruvica	JC	MP	C7806 C7818 C7858 C7865 C7871	P7858 P7871	90	5	90
					MP	C7806 C7818 C7858 C7865 C7871	P7806 P7818 P7865	120	5	120

[49] Schedule 1, entry for Indacaterol with glycopyrronium

omit from the column headed "Circumstances": **C5763** *substitute:* **C7798**

[50] Schedule 1, after entry for Insulin aspart with insulin aspart protamine suspension

insert:

Insulin degludec with insulin aspart	Injections, cartridges, 70 units-30 units per mL, 3 mL, 5	Injection	Ryzodeg Penfill	NO	MP NP		5	1	1
	Injections, pre-filled pen, 70 units-30 units per mL, 3 mL, 5	Injection	Ryzodeg Flextouch	NO	MP NP		5	1	1

[51] Schedule 1, entry for Ipratropium in the form Pressurised inhalation containing ipratropium bromide 21 micrograms per dose, 200 doses (CFC-free formulation)

insert in the column headed "Form" after the word "bromide": **monohydrate**

[52] Schedule 1, entry for Ipratropium in the form Nebuliser solution containing ipratropium bromide 250 micrograms (anhydrous) in 1 mL single dose units, 30

omit from the column headed "Form": **(anhydrous)** *substitute:* **(as monohydrate)**

[53] Schedule 1, entry for Ipratropium in the form Nebuliser solution containing ipratropium bromide 500 micrograms (anhydrous) in 1 mL single dose units, 30

omit from the column headed "Form": **(anhydrous)** *substitute:* **(as monohydrate)**

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[54] Schedule 1, entry for Lamotrigine in the form Tablet 200 mg

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

	a	Sandoz Lamotrigine	HX	MP NP	C5138	56	5	56

[55] Schedule 1, entry for Lercanidipine in the form Tablet containing lercanidipine hydrochloride 10 mg

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

	a	Zircol 10	AL	MP NP		28	5	28

[56] Schedule 1, entry for Lercanidipine in the form Tablet containing lercanidipine hydrochloride 20 mg

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

	a	Zircol 20	AL	MP NP		28	5	28

[57] Schedule 1, entry for Leuprorelin in the form Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 7.5 mg, injection set

omit from the column headed "Responsible Person": **TL** *substitute:* **MF**

[58] Schedule 1, entry for Leuprorelin in the form Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 22.5 mg, injection set

omit from the column headed "Responsible Person": **TL** *substitute:* **MF**

[59] Schedule 1, entry for Leuprorelin in the form Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 30 mg, injection set

omit from the column headed "Responsible Person": **TL** *substitute:* **MF**

[60] Schedule 1, entry for Leuprorelin in the form Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 45 mg, injection set

omit from the column headed "Responsible Person": **TL** *substitute:* **MF**

[61] Schedule 1, entry for Leuprorelin and bicalutamide in the form Pack containing 1 syringe containing leuprorelin 7.5 mg (as acetate) and 28 tablets bicalutamide 50 mg

omit from the column headed "Responsible Person": **TL** *substitute:* **MF**

[62] Schedule 1, entry for Leuprorelin and bicalutamide in the form Pack containing 1 syringe containing leuprorelin 22.5 mg (as acetate) and 28 tablets bicalutamide 50 mg

omit from the column headed "Responsible Person": **TL** *substitute:* **MF**

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[63] **Schedule 1, entry for Leuprorelin and bicalutamide in the form Pack containing 1 syringe containing leuprorelin 22.5 mg (as acetate) and 84 tablets bicalutamide 50 mg**

omit from the column headed "Responsible Person": **TL** *substitute:* **MF**

[64] **Schedule 1, entry for Levetiracetam in the form Tablet 1 g**

omit:

	a	Levitaccord	RA	MP NP	C7603	60	5	60

[65] **Schedule 1, entry for Levodopa with carbidopa**

(a) *omit from the column headed "Form":* **Intestinal gel 20 mg-5 mg per mL, 100 mL**

substitute: **Intestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg per mL, 100 mL**

(b) *omit from the column headed "Form":* **Tablet 100 mg-25 mg (anhydrous)**

substitute: **Tablet 100 mg-25 mg (as monohydrate)**

(c) *omit from the column headed "Form":* **Tablet 200 mg-50 mg (anhydrous) (modified release)**

substitute: **Tablet (modified release) 200 mg-50 mg (as monohydrate)**

(d) *omit from the column headed "Form":* **Tablet 250 mg-25 mg (anhydrous)**

substitute: **Tablet 250 mg-25 mg (as monohydrate)**

[66] **Schedule 1, entry for Levodopa with carbidopa and entacapone**

(a) *omit from the column headed "Form":* **Tablet 50 mg-12.5 mg-200 mg** *substitute:* **Tablet 50 mg-12.5 mg (as monohydrate)-200 mg**

(b) *omit from the column headed "Form":* **Tablet 75 mg-18.75 mg-200 mg** *substitute:* **Tablet 75 mg-18.75 mg (as monohydrate)-200 mg**

(c) *omit from the column headed "Form":* **Tablet 100 mg-25 mg-200 mg** *substitute:* **Tablet 100 mg-25 mg (as monohydrate)-200 mg**

(d) *omit from the column headed "Form":* **Tablet 125 mg-31.25 mg-200 mg** *substitute:* **Tablet 125 mg-31.25 mg (as monohydrate)-200 mg**

(e) *omit from the column headed "Form":* **Tablet 150 mg-37.5 mg-200 mg** *substitute:* **Tablet 150 mg-37.5 mg (as monohydrate)-200 mg**

(f) *omit from the column headed "Form":* **Tablet 200 mg-50 mg-200 mg** *substitute:* **Tablet 200 mg-50 mg (as monohydrate)-200 mg**

[67] **Schedule 1, entry for Meloxicam in the form Tablet 7.5 mg**

omit:

		Meloxicam Ranbaxy	RA	MP NP	C4907 C4962	30	3	30

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[68] Schedule 1, entry for Meloxicam in the form Tablet 15 mg

omit:

	Meloxicam Ranbaxy	RA	MP NP	C4907 C4962	30	3	30	

[69] Schedule 1, entry for Mercaptopurine

(a) *omit from the column headed "Form":* **Oral suspension 20 mg per mL, 100 mL**

substitute: **Oral suspension containing mercaptopurine monohydrate 20 mg per mL, 100 mL**

(b) *omit from the column headed "Form":* **Tablet 50 mg**

substitute: **Tablet containing mercaptopurine monohydrate 50 mg**

[70] Schedule 1, entry for Metformin in the form Tablet containing metformin hydrochloride 1 g

omit:

a	Metformin Ranbaxy 1000	RA	MP NP		90	5	90	

[71] Schedule 1, entry for Methyldopa

omit from the column headed "Form": **Tablet 250 mg** *substitute:* **Tablet 250 mg (as sesquihydrate)**

[72] Schedule 1, entry for Metoclopramide

(a) *omit from the column headed "Form":* **Injection containing metoclopramide hydrochloride 10 mg in 2 mL**

substitute: **Injection containing 10 mg metoclopramide hydrochloride (as monohydrate) in 2 mL**

(b) *omit from the column headed "Form":* **Tablet containing metoclopramide hydrochloride 10 mg**

substitute: **Tablet containing 10 mg metoclopramide hydrochloride (as monohydrate)**

[73] Schedule 1, entry for Moclobemide in the form Tablet 150 mg

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

a	APO-Moclobemide	TX	MP NP	C5650	60	5	60	

[74] Schedule 1, entry for Moclobemide in the form Tablet 300 mg

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

a	APO-Moclobemide	TX	MP NP	C5650	60	5	60	

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[75] Schedule 1, entry for Montelukast in the form Tablet, chewable, 5 mg (as sodium)

omit from the column headed "Circumstances" (all instances): **C6684** *substitute:* **C7781**

[76] Schedule 1, entry for Morphine

substitute:

Morphine	Capsule containing morphine sulfate pentahydrate 10 mg (containing sustained release pellets)	Oral		Kapanol	YN	MP NP	C4556	28	0	28
	Capsule containing morphine sulfate pentahydrate 20 mg (containing sustained release pellets)	Oral		Kapanol	YN	MP NP	C4556	28	0	28
	Capsule containing morphine sulfate pentahydrate 30 mg (controlled release)	Oral		MS Mono	MF	MP NP	C4556	14	0	14
	Capsule containing morphine sulfate pentahydrate 50 mg (containing sustained release pellets)	Oral		Kapanol	YN	MP NP	C4556	28	0	28
	Capsule containing morphine sulfate pentahydrate 60 mg (controlled release)	Oral		MS Mono	MF	MP NP	C4556	14	0	14
	Capsule containing morphine sulfate pentahydrate 90 mg (controlled release)	Oral		MS Mono	MF	MP NP	C4556	14	0	14
	Capsule containing morphine sulfate pentahydrate 100 mg (containing sustained release pellets)	Oral		Kapanol	YN	MP NP	C4556	28	0	28
	Capsule containing morphine sulfate pentahydrate 120 mg (controlled release)	Oral		MS Mono	MF	MP NP	C4556	14	0	14
	Injection containing morphine hydrochloride trihydrate 10 mg in 1 mL	Injection	a	Morphine Juno	JU	PDP MP NP MW		5	0	5
	Injection containing morphine sulfate pentahydrate 10 mg in 1 mL	Injection	a	Hospira Pty Limited	PF	PDP MP NP MW		5	0	5
	Injection containing morphine	Injection		Hospira Pty	PF	PDP MP		5	0	5

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sulfate pentahydrate 15 mg in 1 mL		Limited		NP MW				
Injection containing morphine hydrochloride trihydrate 20 mg in 1 mL	Injection	Morphine Juno	JU	PDP MP NP		5	0	5
Injection containing morphine sulfate pentahydrate 30 mg in 1 mL	Injection	Hospira Pty Limited	PF	PDP MP NP		5	0	5
Injection containing morphine hydrochloride trihydrate 50 mg in 5 mL	Injection	Morphine Juno	JU	MP NP		5	0	5
Injection containing morphine hydrochloride trihydrate 100 mg in 5 mL	Injection	Morphine Juno	JU	MP NP		5	0	5
Injection containing morphine tartrate 120 mg in 1.5 mL	Injection	Hospira Pty Limited	PF	MP NP		5	0	5
Oral solution containing morphine hydrochloride trihydrate 2 mg per mL, 200 mL	Oral	Ordine 2	MF	MP NP	C4959	1	0	1
				PDP	C4926	1	0	1
Oral solution containing morphine hydrochloride trihydrate 5 mg per mL, 200 mL	Oral	Ordine 5	MF	MP NP	C4959	1	0	1
				PDP	C4926	1	0	1
Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 200 mL	Oral	Ordine 10	MF	MP NP	C4959	1	0	1
				PDP	C4926	1	0	1
Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 20 mg per sachet	Oral	MS Contin Suspension 20 mg	MF	MP NP	C4556	28	0	28
Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 30 mg per sachet	Oral	MS Contin Suspension 30 mg	MF	MP NP	C4556	28	0	28
Sachet containing controlled	Oral	MS Contin	MF	MP NP	C4556	28	0	28

release granules for oral suspension, containing morphine sulfate pentahydrate 60 mg per sachet			Suspension 60 mg								
Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 100 mg per sachet	Oral		MS Contin Suspension 100 mg	MF	MP NP	C4556			28	0	28
Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 200 mg per sachet	Oral		MS Contin Suspension 200 mg	MF	MP NP	C4900			28	0	28
Tablet containing morphine sulfate pentahydrate 5 mg (controlled release)	Oral		MS Contin	MF	MP NP	C4556			28	0	28
Tablet containing morphine sulfate pentahydrate 10 mg	Oral		Sevredol	MF	MP NP	C4960 C6168	P4960		20	0	20
					MP NP	C4960 C6168	P6168		20	2	20
Tablet containing morphine sulfate pentahydrate 10 mg (controlled release)	Oral	a	Momex SR 10	RW	MP NP	C4556			28	0	28
		a	Morphine MR AN	EA	MP NP	C4556			28	0	28
		a	MORPHINE MR APOTEX	TX	MP NP	C4556			28	0	28
		a	Morphine MR Mylan	AF	MP NP	C4556			28	0	28
		a	MS Contin	MF	MP NP	C4556			28	0	28
Tablet containing morphine sulfate pentahydrate 15 mg (controlled release)	Oral		MS Contin	MF	MP NP	C4556			28	0	28
Tablet containing morphine sulfate pentahydrate 20 mg	Oral		Sevredol	MF	MP NP	C4960 C6168	P4960		20	0	20
					MP NP	C4960 C6168	P6168		20	2	20
Tablet containing morphine sulfate pentahydrate 30 mg	Oral		Anamorph	RW	MP NP	C4959			20	0	20
					PDP	C4926			20	0	20
Tablet containing morphine	Oral	a	Momex SR 30	RW	MP NP	C4556			28	0	28

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sulfate pentahydrate 30 mg (controlled release)										
		a	Morphine MR AN	EA	MP NP	C4556		28	0	28
		a	MORPHINE MR APOTEX	TX	MP NP	C4556		28	0	28
		a	Morphine MR Mylan	AF	MP NP	C4556		28	0	28
		a	MS Contin	MF	MP NP	C4556		28	0	28
Tablet containing morphine sulfate pentahydrate 60 mg (controlled release)	Oral	a	Momex SR 60	RW	MP NP	C4556		28	0	28
		a	Morphine MR AN	EA	MP NP	C4556		28	0	28
		a	MORPHINE MR APOTEX	TX	MP NP	C4556		28	0	28
		a	Morphine MR Mylan	AF	MP NP	C4556		28	0	28
		a	MS Contin	MF	MP NP	C4556		28	0	28
Tablet containing morphine sulfate pentahydrate 100 mg (controlled release)	Oral	a	Momex SR 100	RW	MP NP	C4556		28	0	28
		a	Morphine MR AN	EA	MP NP	C4556		28	0	28
		a	MORPHINE MR APOTEX	TX	MP NP	C4556		28	0	28
		a	Morphine MR Mylan	AF	MP NP	C4556		28	0	28
		a	MS Contin	MF	MP NP	C4556		28	0	28
Tablet containing morphine sulfate pentahydrate 200 mg (controlled release)	Oral		MS Contin	MF	MP NP	C4900 C6151	P4900	28	0	28
					MP NP	C4900 C6151	P6151	28	2	28

[77] Schedule 1, entry for Moxonidine in the form Tablet 200 micrograms

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

	a	APO-Moxonidine	TX	MP NP	C4944		30	5	30

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[78] Schedule 1, entry for Moxonidine in the form Tablet 400 micrograms

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

a	APO-Moxonidine	TX	MP NP	C4944	30	5	30

[79] Schedule 1, entry for Nebivolol in the form Tablet 1.25 mg (as hydrochloride)

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

a	APO-Nebivolol	TX	MP NP	C5324	56	5	28

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

[80] Schedule 1, entry for Nebivolol in the form Tablet 5 mg (as hydrochloride)

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

a	APO-Nebivolol	TX	MP NP	C5324	28	5	28

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

[81] Schedule 1, entry for Nebivolol in the form Tablet 10 mg (as hydrochloride)

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

a	APO-Nebivolol	TX	MP NP	C5324	28	5	28

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

[82] Schedule 1, entry for Nintedanib in each of the forms: Capsule 100 mg; and Capsule 150 mg

omit from the column headed "Circumstances": **C6970**

[83] Schedule 1, entry for Nivolumab in each of the forms: Injection concentrate for I.V. infusion 40 mg in 4 mL; and Injection concentrate for I.V. infusion 100 mg in 10 mL

(a) *insert in numerical order in the column headed "Circumstances":* **C6996**

(b) *omit from the column headed "Circumstances":* **C7567**

(c) *insert in numerical order in the column headed "Circumstances":* **C7787 C7802 C7864**

[84] Schedule 1, entry for Pegfilgrastim

(a) *omit from the column headed "Circumstances" (all brands):* **C6488 C6489 C6490 C6491 C6492 C6493 C6494 C6501 C6502 C6507 C6512 C6513 C6514 C6515 C6516 C6521 C6522 C6523 C6531 C6532 C6533 C6534 C6535 C6536 C6543 C6544 C6545 C6546 C6554 C6555**

(b) *substitute (all brands):* **C7822 C7823 C7843 C7862**

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[85] Schedule 1, entry for Peginterferon alfa-2a

substitute:

Peginterferon alfa-2a	Injection 135 micrograms in 0.5 mL single use pre-filled syringe	Injection	Pegasys	RO	MP NP			4	5	4	
					MP		P5004 P5010 P5016 P5067	8 CN5004 CN5010 CN5016 CN5067	5 CN5004 CN5010 CN5016 CN5067	4	C(100)
	Injection 180 micrograms in 0.5 mL single use pre-filled syringe	Injection	Pegasys	RO	MP		P6745	4 CN6745	2 CN6745	4	C(100)
					MP NP			4	5	4	
					MP		P5004 P5010 P5016 P5067	8 CN5004 CN5010 CN5016 CN5067	5 CN5004 CN5010 CN5016 CN5067	4	C(100)

[86] Schedule 1, entry for Pembrolizumab in each of the forms: Powder for injection 50 mg; and Solution concentrate for I.V. infusion 100 mg in 4 mL

insert in numerical order in the column headed "Circumstances": **C7773**

[87] Schedule 1, entry for Perampanel

substitute:

Perampanel	Tablet 2 mg (as hemisesquihydrate)	Oral	Fycompa	EI	MP	C4656 C7815		14	1	7
	Tablet 4 mg (as hemisesquihydrate)	Oral	Fycompa	EI	MP NP	C4658 C7789	P7789	28	2	28
					MP NP	C4658 C7789	P4658	28	5	28
	Tablet 6 mg (as hemisesquihydrate)	Oral	Fycompa	EI	MP NP	C4658 C7789	P7789	28	2	28
					MP NP	C4658 C7789	P4658	28	5	28
	Tablet 8 mg (as hemisesquihydrate)	Oral	Fycompa	EI	MP NP	C4658 C7789		28	5	28
	Tablet 10 mg (as hemisesquihydrate)	Oral	Fycompa	EI	MP NP	C4658 C7789		28	5	28
	Tablet 12 mg (as	Oral	Fycompa	EI	MP NP	C4658 C7789		28	5	28

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	hemisesquihydrate)								

[88] Schedule 1, entry for Periciazine

substitute:

Periciazine	Tablet 2.5 mg	Oral	Neulactil	SW	MP NP		100	5	100
	Tablet 2.5 mg, 84	Oral	Neulactil	SW	MP NP		84	5	84
	Tablet 10 mg	Oral	Neulactil	SW	MP NP		100	5	100
	Tablet 10 mg, 84	Oral	Neulactil	SW	MP NP		84	5	84

[89] Schedule 1, entry for Pirfenidone in the form Capsule 267 mg

omit from the column headed circumstances: **C6962**

[90] Schedule 1, after entry for Pirfenidone in the form Capsule 267 mg

insert:

	Tablet 267 mg	Oral	Esbriet	RO	MP	C6950 C6961 C6975	270	5	90
	Tablet 801mg	Oral	Esbriet	RO	MP	C6961	90	5	90

[91] Schedule 1, entry for Piroxicam in the form Capsule 10 mg *[Maximum Quantity: 50; Number of Repeats: 0]*

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

		a	APO-Piroxicam	TX	PDP	C6214	50	0	50

[92] Schedule 1, entry for Piroxicam in the form Capsule 10 mg *[Maximum Quantity: 50; Number of Repeats: 3]*

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

		a	APO-Piroxicam	TX	MP NP	C6214	50	3	50

[93] Schedule 1, entry for Piroxicam in the form Capsule 20 mg *[Maximum Quantity: 25; Number of Repeats: 0]*

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

		a	APO-Piroxicam	TX	PDP	C6214	25	0	25

[94] Schedule 1, entry for Piroxicam in the form Capsule 20 mg *[Maximum Quantity: 25; Number of Repeats: 3]*

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

		a	APO-Piroxicam	TX	MP NP	C6214	25	3	25

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[95] **Schedule 1, entry for Pramipexole in all forms**

omit from the column headed "Form": **hydrochloride** *substitute:* **dihydrochloride monohydrate**

[96] **Schedule 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 40 mg *[Maximum Quantity: 30; Number of Repeats: 5]***

omit:

	a	Pravastatin generichealth	GQ	MP NP			30	5	30

[97] **Schedule 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 40 mg *[Maximum Quantity: 30; Number of Repeats: 11]***

omit:

	a	Pravastatin generichealth	GQ	MP		P7598	30	11	30

[98] **Schedule 1, entry for Quinine**

insert in the column headed "Form" after the word "sulfate": **dihydrate**

[99] **Schedule 1, entry for Rabeprazole in the form Tablet containing rabeprazole sodium 10 mg (enteric coated)**

omit:

	a	Rabeprazole generichealth	GQ	MP NP	C5444 C5512		28	5	28

[100] **Schedule 1, entry for Ramipril in the form Capsule 2.5 mg**

omit:

		Ramipril generichealth	GQ	MP NP			30	5	30

[101] **Schedule 1, entry for Ramipril in the form Capsule 5 mg**

omit:

		Ramipril generichealth	GQ	MP NP			30	5	30

[102] **Schedule 1, entry for Ramipril in the form Capsule 10 mg**

omit:

		Ramipril generichealth	GQ	MP NP			30	5	30

[103] Schedule 1, entry for Riociguat

substitute:

Riociguat	Tablet 500 micrograms	Oral	Adempas	BN	MP	See Note 3	See Note 3	See Note 3	See Note 3	42	D(100)
					MP	See Note 3	See Note 3	See Note 3	See Note 3	84	D(100)
	Tablet 1 mg	Oral	Adempas	BN	MP	See Note 3	See Note 3	See Note 3	See Note 3	42	D(100)
					MP	See Note 3	See Note 3	See Note 3	See Note 3	84	D(100)
	Tablet 1.5 mg	Oral	Adempas	BN	MP	See Note 3	See Note 3	See Note 3	See Note 3	42	D(100)
					MP	See Note 3	See Note 3	See Note 3	See Note 3	84	D(100)
	Tablet 2 mg	Oral	Adempas	BN	MP	See Note 3	See Note 3	See Note 3	See Note 3	42	D(100)
					MP	See Note 3	See Note 3	See Note 3	See Note 3	84	D(100)
	Tablet 2.5 mg	Oral	Adempas	BN	MP	See Note 3	See Note 3	See Note 3	See Note 3	42	D(100)
					MP	See Note 3	See Note 3	See Note 3	See Note 3	84	D(100)

[104] Schedule 1, entry for Tiotropium with olodaterol

omit from the column headed "Circumstances": **C5763** *substitute:* **C7798**

[105] Schedule 1, entry for Umeclidinium with vilanterol

omit from the column headed "Circumstances": **C5763** *substitute:* **C7798**

[106] Schedule 1, entry for Vinblastine

omit:

			Vinblastine Teva	DZ	MP			See Note 3	See Note 3	1	D(100)

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[107] Schedule 3

omit:

TL	Tolmar Australia Pty Ltd	53 162 640 708

[108] Schedule 4, Part 1, entry for Aclidinium with formoterol

substitute:

	C7798			Chronic obstructive pulmonary disease (COPD) Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR Patient must have been stabilised on a combination of a LAMA and a LABA.	Compliance with Authority Required procedures - Streamlined Authority Code 7798

[109] Schedule 4, Part 1, entry for Budesonide with formoterol

(a) *insert in the column headed "Authority Requirements (part of Circumstances; or Conditions)" for Circumstances Code C4380:*

Compliance with Authority Required procedures - Streamlined Authority Code 4380

(b) *insert in the column headed "Authority Requirements (part of Circumstances; or Conditions)" for Circumstances Code C4394:*

Compliance with Authority Required procedures - Streamlined Authority Code 4394

(c) *insert in the column headed "Authority Requirements (part of Circumstances; or Conditions)" for Circumstances Code C4397:*

Compliance with Authority Required procedures - Streamlined Authority Code 4397

(d) *insert in the column headed "Authority Requirements (part of Circumstances; or Conditions)" for Circumstances Code C4404:*

Compliance with Authority Required procedures - Streamlined Authority Code 4404

(e) *insert in the column headed "Authority Requirements (part of Circumstances; or Conditions)" for Circumstances Code C4689:*

Compliance with Authority Required procedures - Streamlined Authority Code 4689

(f) *insert in the column headed "Authority Requirements (part of Circumstances; or Conditions)" for Circumstances Code C7527:*

Compliance with Authority Required procedures - Streamlined Authority Code 7527

(g) *insert in the column headed "Authority Requirements (part of Circumstances; or Conditions)" for Circumstances Code C7574:*

Compliance with Authority Required procedures - Streamlined Authority Code 7574

[110] Schedule 4, Part 1, entry for Fluticasone furoate with vilanterol

(a) *insert in the column headed "Authority Requirements (part of Circumstances; or Conditions)" for Circumstances Code C4689:*

Compliance with Authority Required procedures - Streamlined Authority Code 4689

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(b) *insert in the column headed "Authority Requirements (part of Circumstances; or Conditions)" for Circumstances Code C4711:*

Compliance with Authority Required procedures - Streamlined Authority Code 4711

(c) *insert in the column headed "Authority Requirements (part of Circumstances; or Conditions)" for Circumstances Code C4731:*

Compliance with Authority Required procedures - Streamlined Authority Code 4731

[111] Schedule 4, Part 1, entry for Fluticasone with formoterol

insert in the column headed "Authority Requirements (part of Circumstances; or Conditions)" for Circumstances Code C4395:

Compliance with Authority Required procedures - Streamlined Authority Code 4395

[112] Schedule 4, Part 1, entry for Fluticasone with salmeterol

(a) *insert in the column headed "Authority Requirements (part of Circumstances; or Conditions)" for Circumstances Code C4689:*

Compliance with Authority Required procedures - Streamlined Authority Code 4689

(b) *insert in the column headed "Authority Requirements (part of Circumstances; or Conditions)" for Circumstances Code C4930:*

Compliance with Authority Required procedures - Streamlined Authority Code 4930

[113] Schedule 4, Part 1, after entry for Follitropin beta

insert:

Follitropin delta	C5027			Assisted Reproductive Technology Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.	Compliance with Authority Required procedures - Streamlined Authority Code 5027

[114] Schedule 4, Part 1, after entry for Glatiramer

insert:

Glecaprevir with pibrentasvir	C7593	P7593		Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 8 weeks.	Compliance with Authority Required procedures
	C7594	P7594		Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 16 weeks.	Compliance with Authority Required procedures
	C7615	P7615		Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the	Compliance with Authority Required procedures

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				Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 12 weeks.	

[115] Schedule 4, Part 1, entry for Golimumab

(a) *omit:*

	C7662	P7662		Moderate to severe ulcerative colitis Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND Patient must have a Mayo clinic score greater than or equal to 6; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score). Patient must be aged 18 years or older. Applications for authorisation of initial treatment must be in writing and must include: (a) two completed authority prescription forms; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and (iii) the signed patient acknowledgement. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written providing for a loading dose of 200 mg at week 0 and a dose of 100 mg at week 2. This prescription should specify a quantity of 3 injections of 100 mg and no repeats. The second prescription should be for the subsequent doses at weeks 6 and 10. This prescription should specify a quantity of 1 injection of 100 mg and one repeat. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment. The most recent Mayo clinic or partial Mayo clinic score must be no more than 1 month old at the time of application. Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2, 6 and 10 so that there is adequate time for a response to be demonstrated. Patients must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as	Compliance with Written Authority Required procedures

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				outlined in the restriction for continuing treatment. If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.	

(b) *omit:*

	C7675	P7675		Moderate to severe ulcerative colitis Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with adalimumab, golimumab, infliximab or vedolizumab for this condition in this treatment cycle; AND Patient must not have failed PBS-subsidised therapy with golimumab for this condition in the current treatment cycle. Patient must be aged 18 years or older. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug. Applications for authorisation of change or recommencement treatment must be in writing and must include: (a) two completed authority prescription forms; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) Mayo clinical assessment (to demonstrate response to prior treatment). Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written providing for a loading dose of 200 mg at week 0 and a dose of 100 mg at week 2. This prescription should specify a quantity of 3 injections of 100 mg and no repeats. The second prescription should be for the subsequent doses at weeks 6 and 10. This prescription should specify a quantity of 1 injection of 100 mg and one repeat.	Compliance with Written Authority Required procedures

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

	C7827	P7827		Moderate to severe ulcerative colitis Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND Patient must have a Mayo clinic score greater than or equal to 6; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency	Compliance with Written Authority Required procedures

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				subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score). Patient must be aged 18 years or older. Application for authorisation of initial treatment must be in writing and must include: (a) a completed authority prescription form; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and (iii) the signed patient acknowledgement. The most recent Mayo clinic or partial Mayo clinic score must be no more than 1 month old at the time of application. Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2, 6 and 10 so that there is adequate time for a response to be demonstrated. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment. A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10. Patients must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment. If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.	
	C7853	P7853		Moderate to severe ulcerative colitis Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with adalimumab, golimumab, infliximab or vedolizumab for this condition in this treatment cycle; AND Patient must not have failed PBS-subsidised therapy with golimumab for this condition in the current treatment cycle. Patient must be aged 18 years or older. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug. A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10. Application for authorisation of change or recommencement treatment must be in writing and must include: (a) a completed authority prescription form; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) Mayo clinical assessment (to demonstrate response to prior treatment).	Compliance with Written Authority Required procedures

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[116] Schedule 4, Part 1, entry for Ibrutinib

substitute:

Ibrutinib	C7806	P7806		Mantle cell lymphoma Grandfather treatment Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2018; 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 Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures
	C7818	P7818		Mantle cell lymphoma Initial treatment The condition must have relapsed or be refractory to at least one prior therapy; 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 Patient must not have previously received PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures
	C7858	P7858		Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) 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 develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures
	C7865	P7865		Mantle cell lymphoma 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 develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures
	C7871	P7871		Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Initial treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND The condition must have relapsed or be refractory to at least one prior therapy; AND Patient must have a WHO performance status of 0 or 1; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must be considered unsuitable for treatment or retreatment with a purine analogue. A patient is considered unsuitable for treatment or retreatment with a purine analogue as demonstrated by at least one of the following: a) Failure to respond (stable disease or disease progression on treatment), or a progression-free interval of less than 3 years from treatment with a purine analogue-based therapy and anti-CD20-containing chemoimmunotherapy regimen after at least two cycles; b) Age is 70 years or older; c) Age is 65 years or older and the presence of comorbidities (Cumulative Illness Rating Scale of 6 or greater, or creatinine clearance of less than 70 mL/min) that might place the patient at an unacceptable risk for treatment-related toxicity with purine analogue-based therapy, provided they have received one or more prior treatment including at least two cycles of an alkylating agent-based (or purine analogue-based) anti-CD20 antibody-containing chemoimmunotherapy regimen; d) History of purine analogue-associated autoimmune anaemia or autoimmune thrombocytopenia; e) Evidence of one or more 17p chromosomal deletions demonstrated by fluorescence in situ hybridisation (FISH).	Compliance with Authority Required procedures

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[117] Schedule 4, Part 1, entry for Indacaterol with glycopyrronium

substitute:

Indacaterol with glycopyrronium	C7798			Chronic obstructive pulmonary disease (COPD) Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR Patient must have been stabilised on a combination of a LAMA and a LABA.	Compliance with Authority Required procedures - Streamlined Authority Code 7798

[118] Schedule 4, Part 1, entry for Montelukast

(a) *omit:*

	C6684			Asthma Prevention of condition The condition must be exercise-induced; AND The treatment must be as an alternative to adding salmeterol xinafoate; OR The treatment must be as an alternative to adding eformoterol fumarate; AND The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid; AND Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms. Patient must be aged 6 to 14 years inclusive.	Compliance with Authority Required procedures - Streamlined Authority Code 6684

(b) *substitute:*

	C7781			Asthma Prevention of condition The condition must be exercise-induced; AND The treatment must be as an alternative to adding salmeterol xinafoate; OR The treatment must be an alternative to adding formoterol fumarate; AND The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid; AND Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms. Patient must be aged 6 to 14 years inclusive.	Compliance with Authority Required procedures - Streamlined Authority Code 7781

[119] Schedule 4, Part 1, entry for Nintedanib

(a) *omit:*

	C6950			Idiopathic pulmonary fibrosis Initial treatment 1 - new patient The condition must be diagnosed through a multidisciplinary team; AND Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months; AND Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height; AND Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7; AND Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%; AND Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental	Compliance with Authority Required procedures

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				exposures, connective tissue disease, or drug toxicity; AND The treatment must be the sole PBS-subsidised treatment for this condition. Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician. A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis. Patient must have not have an acute respiratory infection at the time of FVC testing. Applications for authorisation of initial treatment must be in writing and must include: a) a completed authority prescription form; and b) a completed IPF Authority Application Supporting Information Form; and c) a signed patient acknowledgement.	

(b) *substitute:*

	C6950			Idiopathic pulmonary fibrosis Initial treatment 1 - new patient The condition must be diagnosed through a multidisciplinary team; AND Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months; AND Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height; AND Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7; AND Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%; AND Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity; AND The treatment must be the sole PBS-subsidised treatment for this condition. Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician. A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis. Patient must not have an acute respiratory infection at the time of FVC testing. Application for authorisation of initial treatment must be in writing and must include: a) a completed authority prescription form; and b) a completed IPF Authority Application Supporting Information Form; and c) a signed patient acknowledgement.	Compliance with Authority Required procedures

(c) *omit:*

	C6970			Idiopathic pulmonary fibrosis Initial treatment 3 - Grandfathering treatment Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician. Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2017; AND The condition must have been diagnosed through a multidisciplinary team; AND Patient must have had a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height at the time treatment with this drug for this condition was initiated; AND	Compliance with Authority Required procedures

				Patient must have had a forced expiratory volume in 1 second (FEV1)/FVC ratio greater than 0.7 at the time treatment with this drug for this condition was initiated; AND Patient must have had diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30% at the time treatment with this drug for this condition was initiated; AND Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity; AND The treatment must be the sole PBS-subsidised treatment for this condition. A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis. Patient must have not have an acute respiratory infection at the time of FVC testing. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. A patient may qualify for PBS-subsidised treatment under this restriction once only. Applications for authorisation of initial treatment must be in writing and must include: a) a completed authority prescription form; and b) a completed IPF Authority Application Supporting Information Form; and c) a signed patient acknowledgement.	

[120] Schedule 4, Part 1, entry for Nivolumab

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

	C6996			Locally advanced or metastatic non-small cell lung cancer Initial treatment Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor for this condition; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised treatment for this condition; AND The condition must have progressed on or after prior platinum based chemotherapy. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 6996

(b) *omit:*

	C7567			Locally advanced or metastatic non-small cell lung cancer Initial treatment Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised treatment for this condition; AND The condition must have progressed on or after prior platinum based chemotherapy. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 7567

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

	C7787			Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have stable or responding disease; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 7787
	C7802			Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx	Compliance with

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				Grandfather treatment Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 August 2018; AND Patient must have had a WHO performance status of 0 or 1; AND The condition must have progressed within 6 months of the last dose of prior platinum based chemotherapy, prior to commencing non-PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving non-PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition. 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.	Authority Required procedures - Streamlined Authority Code 7802
	C7864			Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx Initial treatment 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 condition must have progressed within 6 months of the last dose of prior platinum based chemotherapy; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor for this condition. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 7864

[121] Schedule 4, Part 1, entry for Pegfilgrastim

substitute:

Pegfilgrastim	C7822			Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must be at greater than 20% risk of developing febrile neutropenia; OR Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 7822
	C7823			Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must be at greater than 20% risk of developing febrile neutropenia; OR Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures
	C7843			Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must have had a prior episode of febrile neutropenia; OR Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 7843
	C7862			Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must have had a prior episode of febrile neutropenia; OR Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures

[122] Schedule 4, Part 1, entry for Peginterferon alfa-2a

(a) *omit from the column headed "Circumstances Code" for Circumstance Code **C5004**:* **C5004**

(b) *insert in the column headed "Conditions Code" for Purpose Code **P5004**:* **CN5004**

(c) *omit from the column headed "Circumstances Code" for Circumstance Code **C5010**:* **C5010**

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(d) *insert in the column headed "Conditions Code" for Purpose Code **P5010**:* **CN5010**

(e) *omit from the column headed "Circumstances Code" for Circumstance Code **C5016**:* **C5016**

(f) *insert in the column headed "Conditions Code" for Purpose Code **P5016**:* **CN5016**

(g) *omit from the column headed "Circumstances Code" for Circumstance Code P5067:* **C5067**

(h) *insert in the column headed "Conditions Code" for Purpose Code **P5067**:* **CN5067**

(i) *omit from the column headed "Circumstances Code" for Circumstance Code **P6745**:* **C6745**

(j) *insert in the column headed "Conditions Code" for Purpose Code **P6745**:* **CN6745**

[123] Schedule 4, Part 1, entry for Pembrolizumab

insert:

	C7773	P7773		Relapsed or Refractory Hodgkin lymphoma Initial treatment - Grandfathered patients Patient must have previously received non-PBS-subsidised treatment with a programmed cell death 1 (PD-1) inhibitor for this condition prior to 1 May 2018; AND Patient must have undergone an autologous stem cell transplant (ASCT) for this condition and have experienced relapsed or refractory disease post ASCT prior to receiving treatment with a PD-1 inhibitor for this condition; OR Patient must not have been suitable for ASCT for this condition and have experienced relapsed or refractory disease following at least 2 prior treatments for this condition prior to receiving treatment with a PD-1 inhibitor for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not exceed a total of 35 cycles in a lifetime. 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. Applications for authorisation of initial treatment must be in writing and must include: (a) a completed authority prescription form; (b) a completed Hodgkin lymphoma pembrolizumab PBS Authority Application for Grandfathered patients.	Compliance with Written Authority Required procedures

[124] Schedule 4, Part 1, entry for Perampanel

(a) *insert in the column headed "Purpose Code" for Circumstance Code **C4658**:* **P4568**

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

	C7789	P7789		Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition. Patient must be aged 12 years or older.	Compliance with Authority Required procedures - Streamlined Authority Code 7789
	C7815			Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures Initial treatment Must be treated by a neurologist. The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs; AND The treatment must be in combination with at least one PBS-subsidised anti-epileptic drug; AND The treatment must be for dose titration purposes. Patient must be aged 12 years or older.	Compliance with Authority Required procedures - Streamlined Authority Code 7815

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[125] Schedule 4, Part 1, entry for Pirfenidone

substitute:

Pirfenidone	C6950			Idiopathic pulmonary fibrosis Initial treatment 1 - new patient The condition must be diagnosed through a multidisciplinary team; AND Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months; AND Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height; AND Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7; AND Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%; AND Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity; AND The treatment must be the sole PBS-subsidised treatment for this condition. Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician. A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis. Patient must not have an acute respiratory infection at the time of FVC testing. Application for authorisation of initial treatment must be in writing and must include: a) a completed authority prescription form; and b) a completed IPF Authority Application Supporting Information Form; and c) a signed patient acknowledgement.	Compliance with Authority Required procedures
	C6961			Idiopathic pulmonary fibrosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised treatment for this condition. Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.	Compliance with Authority Required procedures
	C6975			Idiopathic pulmonary fibrosis Initial treatment 2 - change or re-commencement of treatment Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition; AND The treatment must be the sole PBS-subsidised treatment for this condition. Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.	Compliance with Authority Required procedures

[126] Schedule 4, Part 1, entry for Tiotropium with olodaterol

substitute:

Tiotropium with olodaterol	C7798			Chronic obstructive pulmonary disease (COPD) Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR Patient must have been stabilised on a combination of a LAMA and a LABA.	Compliance with Authority Required procedures - Streamlined Authority Code 7798

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[127] Schedule 4, Part 1, entry for Trastuzumab

(a) *insert in the column headed "Purpose Code" for Circumstance Code **C5024**:* **P5024**

(b) *insert in the column headed "Purpose Code" for Circumstance Code **C5032**:* **P5032**

(c) *insert in the column headed "Purpose Code" for Circumstance Code **C5041**:* **P5041**

(d) *insert in the column headed "Purpose Code" for Circumstance Code **C6060**:* **P6060**

(e) *insert in the column headed "Purpose Code" for Circumstance Code **C6061**:* **P6061**

(f) *insert in the column headed "Purpose Code" for Circumstance Code **C6062**:* **P6062**

(g) *insert in the column headed "Purpose Code" for Circumstance Code **C7717**:* **P7717**

[128] Schedule 4, Part 1, entry for Umeclidinium with vilanterol

substitute:

Umeclidinium with vilanterol	C7798			Chronic obstructive pulmonary disease (COPD) Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR Patient must have been stabilised on a combination of a LAMA and a LABA.	Compliance with Authority Required procedures - Streamlined Authority Code 7798

[129] Schedule 4, Part 1, after entry for Ursodeoxycholic acid

insert:

Ustekinumab	C6378	P6378		Severe psoriatic arthritis Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have severe active psoriatic arthritis; AND Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be an adult. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use,	Compliance with Written Authority Required procedures

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				which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement.	
	C6419	P6419		Severe psoriatic arthritis Initial treatment - Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have a documented history of severe active psoriatic arthritis; AND Patient must have been receiving treatment with this drug for this condition prior to 1 May 2016; AND Patient must be receiving treatment with this drug for this condition at the time of application; AND Patient must have demonstrated a response to treatment as specified in the criteria for continuing PBS-subsidised treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be an adult. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement. A patient may qualify for PBS-subsidised treatment under this restriction once only.	Compliance with Written Authority Required procedures
	C6459	P6459		Severe psoriatic arthritis Continuing treatment Patient must have a documented history of severe active psoriatic arthritis; AND Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle; AND Patient must demonstrate, at the time of application, an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be an adult. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.	Compliance with Written Authority Required procedures

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				For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.	
	C6469	P6469		Severe psoriatic arthritis Initial treatment – Initial 2 (change or recommencement of treatment) Patient must have a documented history of severe active psoriatic arthritis; AND Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be an adult. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug. Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.	Compliance with Written Authority Required procedures

				Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased. Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).	
	C6504	P6504		Severe psoriatic arthritis Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more), Initial 2 (change or recommencement of treatment) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 28 weeks treatment; AND The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions.	Compliance with Authority Required procedures
	C6588	P6588		Severe psoriatic arthritis Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) or Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug under the Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.	Compliance with Authority Required procedures
	C6698	P6698		Severe chronic plaque psoriasis Continuing treatment, Face, hand, foot Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; AND Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle; AND Patient must have demonstrated an adequate response to their most recent course of treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or	Compliance with Written Authority Required procedures

				ustekinumab. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value. All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.	
	C6699	P6699		Severe chronic plaque psoriasis Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab. Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.	Compliance with Written Authority Required procedures

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				Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 1 month old at the time of application. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and (iii) the signed patient and prescriber acknowledgements. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.	
	C6700	P6700		Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years) restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 28 weeks treatment; AND The treatment must be as systemic monotherapy (other than methotrexate); AND The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions. Must be treated by a dermatologist.	Compliance with Authority Required procedures
	C6758	P6758		Severe chronic plaque psoriasis Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND The treatment must be as systemic monotherapy (other than methotrexate). Must be treated by a dermatologist.	Compliance with Authority Required procedures
	C6783	P6783		Severe chronic plaque psoriasis	Compliance with Written

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				Continuing treatment, Whole body Patient must have a documented history of severe chronic plaque psoriasis; AND Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle; AND Patient must have demonstrated an adequate response to their most recent course of treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle. All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.	Authority Required procedures
	C6784	P6784		Severe chronic plaque psoriasis Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more) Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); AND The treatment must be as systemic monotherapy (other than methotrexate); AND	Compliance with Written Authority Required procedures

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				Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab. Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 1 month old at the time of application. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and (iii) the signed patient and prescriber acknowledgements. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.	
	C6794	P6794		Severe chronic plaque psoriasis Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years) Patient must have a documented history of severe chronic plaque psoriasis; AND Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.	Compliance with Written Authority Required procedures

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				The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised. Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.	
	C6795	P6795		Severe chronic plaque psoriasis Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; AND Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised. Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or	Compliance with Written Authority Required procedures

				(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.	
	C7035	P7035		Severe Crohn disease Initial PBS-subsidised treatment (Grandfather) Patient must have a documented history of severe Crohn disease; AND Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 September 2017; AND Patient must be receiving treatment with ustekinumab at the time of application; AND Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient. Patient must be aged 18 years or older. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease Grandfathered PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iv) the date of the most recent clinical assessment; and (v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks	Compliance with Written Authority Required procedures

				If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase. A patient may qualify for PBS-subsidised treatment under this restriction once only.	
	C7049	P7049		Severe Crohn disease Balance of supply for Initial treatment, Continuing treatment or Grandfathered treatment Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 16 weeks of treatment; OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR Patient must have received insufficient therapy with this drug under the Grandfathered treatment restriction to complete 24 weeks of treatment. Patient must be aged 18 years or older. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services.	Compliance with Authority Required procedures
	C7059	P7059		Severe Crohn disease Change or Re-commencement of treatment (initial 2) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have a documented history of severe Crohn disease; AND Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment; and (iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction. Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment	Compliance with Written Authority Required procedures

				must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD. A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised. The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.	
	C7061	P7061		Severe Crohn disease Continuing treatment Patient must have a documented history of severe Crohn disease; AND Patient must have previously been issued with an authority prescription for this drug for this condition; AND Patient must have demonstrated or sustained an adequate response to treatment with this drug; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient. Patient must be aged 18 years or older. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment. All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats;	Compliance with Written Authority Required procedures

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				up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks. If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.	
	C7463	P7463		Severe Crohn disease Initial treatment (new patient - initial 1) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months; AND Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iv) the date of the most recent clinical assessment; and (v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:(a) patient must have evidence of intestinal inflammation;(b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii)	Compliance with Written Authority Required procedures

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				faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application. If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. Details of the accepted toxicities including severity can be found on the Department of Human Services website. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised. The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.	

[130] Schedule 4, Part 3, Section 3, Treatment regimen

omit table and substitute:

Item	Kind of patient	Regimen
1	Patient: (a) with Genotype 1; and (b) who is treatment naïve; and (c) who is non-cirrhotic	Either: (a) LEDIPASVIR with SOFOSBUVIR for 8 weeks; or (b) LEDIPASVIR with SOFOSBUVIR for 12 weeks; or (c) DACLATASVIR and SOFOSBUVIR for 12 weeks; or (d) SOFOSBUVIR and PEGINTERFERON ALFA-2A and RIBAVIRIN for 12 weeks; or (e) PARITAPREVIR with RITONAVIR with OMBITASVIR and DASABUVIR for 12 weeks; or (f) PARITAPREVIR with RITONAVIR with OMBITASVIR and DASABUVIR and RIBAVIRIN for 12 weeks; or (g) GRAZOPREVIR with ELBASVIR for 12 weeks; or (h) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (i) GLECAPREVIR with PIBRENTASVIR for 8 weeks.

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2	Patient: (a) with Genotype 1; and (b) who is treatment experienced; and (c) who is non-cirrhotic	Either: (a) LEDIPASVIR with SOFOSBUVIR for 12 weeks; or (b) DACLATASVIR and SOFOSBUVIR for 12 weeks; or (c) DACLATASVIR and SOFOSBUVIR for 24 weeks; or (d) SOFOSBUVIR and PEGINTERFERON ALFA-2A and RIBAVIRIN for 12 weeks; or (e) PARITAPREVIR with RITONAVIR with OMBITASVIR and DASABUVIR for 12 weeks; or (f) PARITAPREVIR with RITONAVIR with OMBITASVIR and DASABUVIR and RIBAVIRIN for 12 weeks; or (g) GRAZOPREVIR with ELBASVIR for 12 weeks; or (h) GRAZOPREVIR with ELBASVIR and RIBAVIRIN for 16 weeks; or (i) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (j) GLECAPREVIR with PIBRENTASVIR for 8 weeks; or (k) GLECAPREVIR with PIBRENTASVIR for 12 weeks; or (l) GLECAPREVIR with PIBRENTASVIR for 16 weeks.
3	Patient: (a) with Genotype 2; and (b) who is treatment naïve; and (c) who is non-cirrhotic	Either: (a) SOFOSBUVIR and RIBAVIRIN for 12 weeks; or (b) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (c) GLECAPREVIR with PIBRENTASVIR for 8 weeks.
4	Patient: (a) with Genotype 2; and (b) who is treatment experienced; and (c) who is non-cirrhotic	Either: (a) SOFOSBUVIR and RIBAVIRIN for 12 weeks; or (b) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (c) GLECAPREVIR with PIBRENTASVIR for 8 weeks.
5	Patient: (a) with Genotype 3; and (b) who is treatment naïve; and (c) who is non-cirrhotic	Either: (a) DACLATASVIR and SOFOSBUVIR for 12 weeks; or (b) SOFOSBUVIR and RIBAVIRIN for 24 weeks; or (c) SOFOSBUVIR and PEGINTERFERON ALFA-2A and RIBAVIRIN for 12 weeks; or (d) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (e) GLECAPREVIR with PIBRENTASVIR for 8 weeks.
6	Patient: (a) with Genotype 3; and (b) who is treatment experienced; and (c) who is non-cirrhotic	Either: (a) DACLATASVIR and SOFOSBUVIR for 12 weeks; or (b) SOFOSBUVIR and RIBAVIRIN for 24 weeks; or (c) SOFOSBUVIR and PEGINTERFERON ALFA-2A and RIBAVIRIN for 12 weeks; or (d) SOFOSBUVIR with VELPATASVIR for 12 weeks; or

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		(e) GLECAPREVIR with PIBRENTASVIR for 16 weeks.
7	Patient: (a) with Genotype 4; and (b) who is treatment naïve; and (c) who is non-cirrhotic	Either: (a) SOFOSBUVIR and PEGINTERFERON ALFA-2A and RIBAVIRIN for 12 weeks; or (b) GRAZOPREVIR with ELBASVIR for 12 weeks; or (c) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (d) GLECAPREVIR with PIBRENTASVIR for 8 weeks.
8	Patient: (a) with Genotype 4; and (b) who is treatment experienced; and (c) who is non-cirrhotic	Either: (a) SOFOSBUVIR and PEGINTERFERON ALFA-2A and RIBAVIRIN for 12 weeks; or (b) GRAZOPREVIR with ELBASVIR for 12 weeks; or (c) GRAZOPREVIR with ELBASVIR and RIBAVIRIN for 16 weeks; or (d) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (e) GLECAPREVIR with PIBRENTASVIR for 8 weeks.
9	Patient: (a) with: (i) Genotype 5; or (ii) Genotype 6; and (b) who is treatment naïve; and (c) who is non-cirrhotic	Either: (a) SOFOSBUVIR and PEGINTERFERON ALFA-2A and RIBAVIRIN for 12 weeks; or (b) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (c) GLECAPREVIR with PIBRENTASVIR for 8 weeks.
10	Patient: (a) with: (i) Genotype 5; or (ii) Genotype 6; and (b) who is treatment experienced; and (c) who is non-cirrhotic	Either: (a) SOFOSBUVIR and PEGINTERFERON ALFA-2A and RIBAVIRIN for 12 weeks; or (b) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (c) GLECAPREVIR with PIBRENTASVIR for 8 weeks.
11	Patient: (a) with Genotype 1; and (b) who is treatment naïve; and (c) who is cirrhotic	Either: (a) LEDIPASVIR with SOFOSBUVIR for 12 weeks; or (b) DACLATASVIR and SOFOSBUVIR and RIBAVIRIN for 12 weeks; or (c) DACLATASVIR and SOFOSBUVIR for 24 weeks; or (d) SOFOSBUVIR and PEGINTERFERON ALFA-2A and RIBAVIRIN for 12 weeks; or (e) PARITAPREVIR with RITONAVIR with OMBITASVIR and DASABUVIR and RIBAVIRIN for 12 weeks; or (f) GRAZOPREVIR with ELBASVIR for 12 weeks; or

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		(g) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (h) GLECAPREVIR with PIBRENTASVIR for 12 weeks.
12	Patient: (a) with Genotype 1; and (b) who is treatment experienced; and (c) who is cirrhotic	Either: (a) LEDIPASVIR with SOFOSBUVIR for 24 weeks; or (b) DACLATASVIR and SOFOSBUVIR for 24 weeks; or (c) DACLATASVIR and SOFOSBUVIR and RIBAVIRIN for 12 weeks; or (d) SOFOSBUVIR and PEGINTERFERON ALFA-2A and RIBAVIRIN for 12 weeks; or (e) PARITAPREVIR with RITONAVIR with OMBITASVIR and DASABUVIR and RIBAVIRIN for 12 weeks; or (f) PARITAPREVIR with RITONAVIR with OMBITASVIR and DASABUVIR and RIBAVIRIN for 24 weeks; or (g) GRAZOPREVIR with ELBASVIR for 12 weeks; or (h) GRAZOPREVIR with ELBASVIR and RIBAVIRIN for 16 weeks; or (i) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (j) GLECAPREVIR with PIBRENTASVIR for 12 weeks; or (k) GLECAPREVIR with PIBRENTASVIR for 16 weeks.
13	Patient: (a) with Genotype 2; and (b) who is treatment naïve; and (c) who is cirrhotic	Either: (a) SOFOSBUVIR and RIBAVIRIN for 12 weeks; or (b) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (c) GLECAPREVIR with PIBRENTASVIR for 12 weeks.
14	Patient: (a) with Genotype 2; and (b) who is treatment experienced; and (c) who is cirrhotic	Either: (a) SOFOSBUVIR and RIBAVIRIN for 12 weeks; or (b) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (c) GLECAPREVIR with PIBRENTASVIR for 12 weeks.
15	Patient: (a) with Genotype 3; and (b) who is treatment naïve; and (c) who is cirrhotic	Either: (a) SOFOSBUVIR and RIBAVIRIN for 24 weeks; or (b) DACLATASVIR and SOFOSBUVIR for 24 weeks; or (c) SOFOSBUVIR and PEGINTERFERON ALFA-2A and RIBAVIRIN for 12 weeks; or (d) DACLATASVIR and SOFOSBUVIR and RIBAVIRIN for 12 weeks; or (e) DACLATASVIR and SOFOSBUVIR and RIBAVIRIN for 24 weeks; or (f) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (g) GLECAPREVIR with PIBRENTASVIR for 12 weeks.

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16	Patient: (a) with Genotype 3; and (b) who is treatment experienced; and (c) who is cirrhotic	Either: (a) DACLATASVIR and SOFOSBUVIR for 24 weeks; or (b) SOFOSBUVIR and RIBAVIRIN for 24 weeks; or (c) SOFOSBUVIR and PEGINTERFERON ALFA-2A and RIBAVIRIN for 12 weeks; or (d) DACLATASVIR and SOFOSBUVIR and RIBAVIRIN for 12 weeks; or (e) DACLATASVIR and SOFOSBUVIR and RIBAVIRIN for 24 weeks; or (f) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (g) GLECAPREVIR with PIBRENTASVIR for 16 weeks.
17	Patient: (a) with Genotype 4; and (b) who is treatment naïve; and (c) who is cirrhotic	Either: (a) SOFOSBUVIR and PEGINTERFERON ALFA-2A and RIBAVIRIN for 12 weeks; or (b) GRAZOPREVIR with ELBASVIR for 12 weeks; or (c) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (d) GLECAPREVIR with PIBRENTASVIR for 12 weeks.
18	Patient: (a) with Genotype 4; and (b) who is treatment experienced; and (c) who is cirrhotic	Either: (a) SOFOSBUVIR and PEGINTERFERON ALFA-2A and RIBAVIRIN for 12 weeks; or (b) GRAZOPREVIR with ELBASVIR for 12 weeks; or (c) GRAZOPREVIR with ELBASVIR and RIBAVIRIN for 16 weeks; or (d) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (e) GLECAPREVIR with PIBRENTASVIR for 12 weeks.
19	Patient: (a) with: (i) Genotype 5; or (ii) Genotype 6; and (b) who is treatment naïve; and (c) who is cirrhotic	Either: (a) SOFOSBUVIR and PEGINTERFERON ALFA-2A and RIBAVIRIN for 12 weeks; or (b) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (c) GLECAPREVIR with PIBRENTASVIR for 12 weeks.
20	Patient: (a) with: (i) Genotype 5; or (ii) Genotype 6; and (b) who is treatment experienced; and (c) who is cirrhotic	Either: (a) SOFOSBUVIR and PEGINTERFERON ALFA-2A and RIBAVIRIN for 12 weeks; or (b) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (c) GLECAPREVIR with PIBRENTASVIR for 12 weeks.

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[131] Schedule 5, entry for Clopidogrel in the form Tablet 75 mg (as hydrogen sulfate) *[GRP-15475]*

insert in alphabetical order in the column headed "Brand": **Clopidogrel Sandoz**

[132] Schedule 5, after entry for Desvenlafaxine in the form Tablet (modified release) 100 mg (as benzoate) *[GRP-16219]*

insert:

	GRP-16220	Tablet (extended release) 50 mg (as succinate)	Oral	Pristiq
		Tablet (modified release) 50 mg	Oral	DESVEN Desfax Desvenlafaxine Actavis Desvenlafaxine Sandoz
		Tablet (modified release) 50 mg (as benzoate)	Oral	APO-Desvenlafaxine MR Desvenlafaxine GH XR

[133] Schedule 5, entry for Doxycycline in each of the forms: Capsule 100 mg (as hydrochloride) (containing enteric coated pellets); and Tablet 100 mg (as hydrochloride) *[GRP-14639]*

omit from the column headed "Form": **hydrochloride** *substitute:* **hyclate**

[134] Schedule 5, entry for Doxycycline in the form Capsule 100 mg (as hydrochloride) (containing enteric coated pellets) *[GRP-14639]*

omit from the column headed "Form": **hydrochloride** *substitute:* **hyclate**

[135] Schedule 5, omit entry for Doxycycline, GRP-15555

[136] Schedule 5, entry for Doxycycline in each of the forms: Capsule 50 mg (as hydrochloride) (containing enteric coated pellets); and Tablet 50 mg (as hydrochloride) *[GRP-15635]*

omit from the column headed "Form": **hydrochloride** *substitute:* **hyclate**

[137] Schedule 5, after entry for Fentanyl in the form Transdermal patch 2.063 mg *[GRP-15898]*

insert:

		Transdermal patch 2.1 mg	Transdermal	APO-Fentanyl Durogesic 12 Fentanyl Sandoz

[138] Schedule 5, entry for Meloxicam in each of the forms: Tablet 15 mg *[GRP-15468]*; Tablet 7.5 mg *[GPR-15658]*

omit from the column headed "Brand": **Meloxicam Ranbaxy**

[139] Schedule 5, entry for Morphine in the form Injection containing morphine hydrochloride 10 mg in 1 mL *[GRP-20890]*

insert in the column headed "Form" after the word "hydrochloride": **trihydrate**

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[140] **Schedule 5, entry for Morphine in the form Injection containing morphine sulfate 10 mg in 1 mL *[GRP-20890]***

insert in the column headed "Form" after the word "sulfate": **pentahydrate**

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

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

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

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

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

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

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