PB 43 of 2023

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 5)

National Health Act 1953

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

Dated 30 May 2023

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

Contents

1 Name

(1) This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 5)*.

(2) This Instrument may also be cited as PB 43 of 2023.

2 Commencement

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

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. *The whole of this instrument*	*1 June 2023*	*1 June 2023*

Note: This table relates only to the provisions of this instrument as originally made.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

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

3 Authority

This instrument is made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

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

[1] Schedule 1, Part 1, entry for Ambrisentan in the form Tablet 5 mg

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

			a	Ambrisentan Viatris	AL	MP	See Note 3	See Note 3	See Note 3	See Note 3	30	D(100)

[2] Schedule 1, Part 1, entry for Amisulpride in the form Tablet 200 mg

omit:

			a	Amisulpride 200 Winthrop	WA	MP NP	C4246		60	5	60

[3] Schedule 1, Part 1, entry for Amlodipine in each of the forms: Tablet 5 mg (as besilate); and Tablet 10 mg (as besilate)

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

			a	Blooms Amlodipine	BG	MP NP			30	5	30

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

substitute:

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

			Pro Pharmaceuticals)							
				PDP	C5833 C5894		10	0	20	
		Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs)	QZ	MP NP	C5832 C5893 C10413	P5832 P5893	10	0	20	
				PDP	C5833 C5894		10	0	20	
		Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Medsurge)	DZ	MP NP	C5832 C5893 C10413	P10413	20	0	20	
		Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals)	QY	MP NP	C5832 C5893 C10413	P10413	20	0	20	
		Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs)	QZ	MP NP	C5832 C5893 C10413	P10413	20	0	20	

[5] Schedule 1, Part 1, entry for Apalutamide

insert in numerical order in the column headed "Circumstances": **C14034**

[6] Schedule 1, Part 1, entry for Azacitidine

(a) *omit:*

	a	AZACITIDINE DR.REDDY'S	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

(b) *omit:*

		a	Azadine	RZ	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

[7] **Schedule 1, Part 1, entry for Baricitinib in the form Tablet 2 mg *[Maximum Quantity: 28; Number of Repeats: 5]***

omit from the column headed "Pack Quantity": **3** *substitute:* **28**

[8] **Schedule 1, Part 1, entry for Bimatoprost in the form Eye drops 300 micrograms per mL, single dose units 0.4 mL, 30**

omit from the column headed "Responsible Person": **AG** *substitute:* **VE**

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

omit from the column headed "Responsible Person" for the brand "Lumigan": **AG** *substitute:* **VE**

[10] **Schedule 1, Part 1, entry for Bimatoprost with timolol in each of the forms: Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, single dose units 0.4 mL, 30; and Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, 3 mL**

omit from the column headed "Responsible Person": **AG** *substitute:* **VE**

[11] **Schedule 1, Part 1, entry for Bortezomib in the form Powder for injection 3.5 mg**

omit:

			Bortezomib-Dr.Reddy's	RI	MP	C11099 C13745		See Note 3	See Note 3	1	D(100)

[12] **Schedule 1, Part 1, entry for Botulinum toxin type A purified neurotoxin complex**

omit from the column headed "Responsible Person": **AG** *substitute:* **VE**

[13] **Schedule 1, Part 1, entry for Brimonidine in the form Eye drops containing brimonidine tartrate 1.5 mg per mL, 5 mL**

omit from the column headed "Responsible Person": **AG** *substitute:* **VE**

[14] **Schedule 1, Part 1, entry for Brimonidine in the form Eye drops containing brimonidine tartrate 2 mg per mL, 5 mL**

(a) *omit from the column headed "Responsible Person" for the brand "Alphagan":* **AG** *substitute:* **VE**

(b) *omit from the column headed "Responsible Person" for the brand "Enidin":* **PE** *substitute:* **VB**

[15] **Schedule 1, Part 1, entry for Brimonidine with timolol**

omit from the column headed "Responsible Person": **AG** *substitute:* **VE**

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

insert in numerical order in the column headed "Circumstances": **C14047**

[17] Schedule 1, Part 1, entry for Carmellose

substitute:

Carmellose	Eye drops containing carmellose sodium 5 mg per mL, single dose units 0.4 mL, 30	Application to the eye	a	Cellufresh	VE	MP NP AO	C6172		3	5	1
			a	Optifresh Tears	PP	MP NP AO	C6172		3	5	1
	Eye drops containing carmellose sodium 5 mg per mL, 10 mL	Application to the eye		Evolve Carmellose	CX	MP NP AO	C6172		1	5	1
	Eye drops containing carmellose sodium 5 mg per mL, 15 mL	Application to the eye		Refresh Tears Plus	VE	AO	C6120		1	5	1
						MP	C6073 C6098	P6073	1	5	1
						NP	C6073		1	5	1
						MP	C6073 C6098	P6098	1	11	1
	Eye drops containing carmellose sodium 10 mg per mL, single dose units 0.4 mL, 30	Application to the eye	a	Celluvisc	VE	MP NP AO	C6172		3	5	1
			a	Optifresh Plus	PP	MP NP AO	C6172		3	5	1
	Eye drops containing carmellose sodium 10 mg per mL, 15 mL	Application to the eye		Refresh Liquigel	VE	AO	C6120		1	5	1
						MP	C6073 C6098	P6073	1	5	1
						NP	C6073		1	5	1
						MP	C6073 C6098	P6098	1	11	1

[18] Schedule 1, Part 1, entry for Carmellose with glycerin

omit from the column headed "Responsible Person": **AG** *substitute:* **VE**

[19] **Schedule 1, Part 1, entry for Cefalexin in the form Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL**

omit from the column headed "Schedule Equivalent" (all instances): **a**

[20] **Schedule 1, Part 1, after entry for Cefalexin in the form Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL *[Maximum Quantity: 1; Number of Repeats: 1]***

insert:

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

[21] **Schedule 1, Part 1, entry for Ceftriaxone in the form Powder for injection 1 g (as sodium)**

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

		a	Ceftriaxone Viatris	AL	MP NP	C5830 C5862 C5868	5	0	5
					MP NP	C5830 C5862 C5868	5	0	10

[22] **Schedule 1, Part 1, entry for Ceftriaxone in the form Powder for injection 2 g (as sodium)**

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

		a	Ceftriaxone Viatris	AL	MP NP	C5826 C5881 C5890	5	0	5
					MP NP	C5826 C5881 C5890	5	0	10

[23] **Schedule 1, Part 1, after entry for Ciclosporin in the form Capsule 100 mg *[Maximum Quantity: 120; Number of Repeats: 5]***

insert:

	Eye drops 900 micrograms per mL, single dose units 0.25 mL, 60	Application to the eye	Cequa	RA	MP AO	C14026 C14032	1	5	1

[24] **Schedule 1, Part 1, entry for Ciclosporin in the form Eye drops 1 mg per mL, single dose units 0.3 mL, 30**

omit from the column headed "Circumstances": **C12284 C12346** *substitute:* **C14026 C14032**

[25] Schedule 1, Part 1, entry for Ciprofloxacin in the form Tablet 500 mg (as hydrochloride)

omit:

	a	Ciprofloxacin GH	HQ	MP NP	C5614 C5615 C5687 C5688 C5689 C5722 C5780	14	0	14

[26] Schedule 1, Part 1, entry for Dexamethasone in the form Intravitreal injection 700 micrograms

omit from the column headed "Responsible Person": **AG** *substitute:* **VE**

[27] Schedule 1, Part 1, after entry for Disopyramide in the form Capsule 100 mg

insert:

Capsule 100 mg (s19A)	Oral	Rythmodan (Canada)	OJ	MP NP		100	5	84

[28] Schedule 1, Part 1, entry for Donepezil in each of the forms: Tablet containing donepezil hydrochloride 5 mg; and Tablet containing donepezil hydrochloride 10 mg

omit:

	a	Donepezil-DRLA	RZ	MP	C13938 C13940 C13941	28	5	28
				NP	C13938	28	5	28

[29] Schedule 1, Part 1, entry for Dosulepin in the form Capsule containing dosulepin hydrochloride 25 mg

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

	a	Dosulepin Viatris	MQ	MP NP		50	2	50

[30] Schedule 1, Part 1, entry for Escitalopram in each of the forms: Tablet 10 mg (as oxalate); and Tablet 20 mg (as oxalate)

omit from the column headed "Circumstances": **C4755** *substitute:* **C4690 C4703 C4755 C4756 C4757**

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

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

	a	BTC Ezetimibe	BG	MP NP	C7966 C7990	30	5	30

					C7996				

[32] **Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 2.063 mg**

omit from the column headed "Responsible Person": **ZP** *substitute:* **RW**

[33] **Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 4.125 mg**

omit from the column headed "Responsible Person": **ZP** *substitute:* **RW**

[34] **Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 8.25 mg**

omit from the column headed "Responsible Person": **ZP** *substitute:* **RW**

[35] **Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 12.375 mg**

omit from the column headed "Responsible Person": **ZP** *substitute:* **RW**

[36] **Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 16.5 mg**

omit from the column headed "Responsible Person": **ZP** *substitute:* **RW**

[37] **Schedule 1, Part 1, entry for Fingolimod in the form Capsule 500 micrograms (as hydrochloride)**

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

		a	Fingolimod-Teva	TB	MP	C10162 C10172	28	5	28

[38] **Schedule 1, Part 1, entry for Fluorometholone in the form Eye drops 1 mg per mL, 5 mL**

omit from the column headed "Responsible Person": **AG** *substitute:* **VE**

[39] **Schedule 1, Part 1, entry for Fluticasone propionate with salmeterol in the form Powder for oral inhalation in breath actuated device containing fluticasone propionate 500 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses**

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

		a	Fluticasone Salmeterol Ciphaler 500/50	LR	MP NP	C4930 C10121	1	5	1

[40] **Schedule 1, Part 1, entry for Fosaprepitant**

(a) *insert in the column headed "Schedule Equivalent" for the brand "Emend IV":* **a**

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

			a	FOSAPREPITANT-AFT	AE	MP NP	C6852 C6886 C6887 C6891		1	5	1	

[41] Schedule 1, Part 1, entry for Gentamicin in the form Eye drops 3 mg (as sulfate) per mL, 5 mL

omit from the column headed "Responsible Person": **AG** *substitute:* **VE**

[42] Schedule 1, Part 1, entry for Gliclazide in the form Tablet 60 mg (modified release)

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

			a	Gliclazide Lupin MR	GQ	MP NP			60	5	60	

[43] Schedule 1, Part 1, entry for Labetalol

omit:

	Tablet containing labetalol hydrochloride 200 mg	Oral	a	Trandate	AS	MP NP			100	5	100	

[44] Schedule 1, Part 1, after entry for Larotrectinib in the form Capsule 100 mg (as sulfate) *[Maximum Quantity: 56; Number of Repeats: 5]*

insert:

	Oral solution 20 mg per mL (as sulfate), 50 mL, 2	Oral		VITRAKVI	BN	MP	C12980 C12981 C12982	P12981 P12982	1	2	1	
						MP	C12980 C12981 C12982	P12980	1	5	1	

[45] Schedule 1, Part 1, entry for Leflunomide in the form Tablet 10 mg

omit from the column headed "Responsible Person" for the brand "Lunava 10": **ZP** *substitute:* **RW**

[46] Schedule 1, Part 1, entry for Leflunomide in the form Tablet 20 mg

omit from the column headed "Responsible Person" for the brand "Lunava 20": **ZP** *substitute:* **RW**

[47] Schedule 1, Part 1, entry for Lenalidomide

substitute:

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

			MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
			MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
	Lenalide	JU	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
			MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
			MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
	Lenalidomide Dr.Reddy's	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
			MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
			MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
	Lenalidomide Sandoz	SZ	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
			MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
			MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
	Lenalidomide-Teva	TB	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
			MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
			MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
	Lenalidomide Viatris	AF	MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)

		Revlimid	CJ	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
Capsule 10 mg	Oral	Cipla Lenalidomide	LR	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
		Lenalide	JU	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
		Lenalidomide Dr.Reddy's	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
		Lenalidomide Sandoz	SZ	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)

		Lenalidomide-Teva	TB	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
		Lenalidomide Viatris	AF	MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
		Revlimid	CJ	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
Capsule 15 mg	Oral	Cipla Lenalidomide	LR	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
		Lenalide	JU	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
		Lenalidomide Dr.Reddy's	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)

				MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
		Lenalidomide Sandoz	SZ	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
		Lenalidomide-Teva	TB	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
		Lenalidomide Viatris	AF	MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
		Revlimid	CJ	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
Capsule 25 mg	Oral	Cipla Lenalidomide	LR	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
		Lenalide	JU	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
				MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)

Lenalidomide Dr.Reddy's	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
		MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
Lenalidomide Sandoz	SZ	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
		MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
Lenalidomide-Teva	TB	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
		MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
Lenalidomide Viatris	AF	MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
Revlimid	CJ	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
		MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)

[48] **Schedule 1, Part 1, entry for Lenvatinib in the form Capsule 4 mg (as mesilate)** ***[Maximum Quantity: 30; Number of Repeats: 2]***

insert in numerical order in the column headed "Circumstances": **C14041 C14042 C14043**

[49] **Schedule 1, Part 1, entry for Lenvatinib in the form Capsule 4 mg (as mesilate)** ***[Maximum Quantity: 60; Number of Repeats: 2]***

(a) *insert in numerical order in the column headed "Circumstances":* **C14041 C14042 C14043**

(b) *insert in numerical order in the column headed "Purposes":* **P14041 P14042 P14043**

[50] **Schedule 1, Part 1, entry for Lenvatinib in the form Capsule 4 mg (as mesilate)** ***[Maximum Quantity: 90; Number of Repeats: 2]***

insert in numerical order in the column headed "Circumstances": **C14041 C14042 C14043**

[51] **Schedule 1, Part 1, entry for Lenvatinib in the form Capsule 10 mg (as mesilate)**

insert in numerical order in the column headed "Circumstances": **C14041 C14042 C14043**

[52] Schedule 1, Part 1, entry for Levonorgestrel with ethinylestradiol in the form Pack containing 6 tablets 50 micrograms-30 micrograms, 5 tablets 75 micrograms-40 micrograms, 10 tablets 125 micrograms-30 micrograms and 7 inert tablets

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

(b) *omit from the column headed "Schedule Equivalent" for the brand "Trifeme 28":* **a**

(c) *omit:*

			a	Triphasil 28	PF	MP NP	4	2	4

(d) *omit from the column headed "Schedule Equivalent" for the brand "Triquilar ED":* **b** *substitute:* **a**

[53] Schedule 1, Part 1, entry for Levothyroxine

substitute:

Levothyroxine	Tablet containing 50 micrograms anhydrous levothyroxine sodium	Oral	b	Eltroxin	LT	MP NP	200	1	200
			a	Eutroxsig	LN	MP NP	200	1	200
			b	Levothox	AF	MP NP	200	1	200
			a	LEVOXINE	RA	MP NP	200	1	200
			a	Oroxine	AS	MP NP	200	1	200
	Tablet containing 75 micrograms anhydrous levothyroxine sodium	Oral	b	Eltroxin	LT	MP NP	200	1	200
			a	Eutroxsig	LN	MP NP	200	1	200
			b	Levothox	AF	MP NP	200	1	200
			a	LEVOXINE	RA	MP NP	200	1	200
			a	Oroxine	AS	MP NP	200	1	200
	Tablet containing 100 micrograms anhydrous levothyroxine sodium	Oral	b	Eltroxin	LT	MP NP	200	1	200
			a	Eutroxsig	LN	MP NP	200	1	200

			b	Levothox	AF	MP NP		200	1	200
			a	LEVOXINE	RA	MP NP		200	1	200
			a	Oroxine	AS	MP NP		200	1	200
	Tablet containing 125 micrograms anhydrous levothyroxine sodium	Oral	a	Eltroxin	LT	MP NP		200	1	200
			a	Levothox	AF	MP NP		200	1	200
	Tablet containing 200 micrograms anhydrous levothyroxine sodium	Oral	b	Eltroxin	LT	MP NP		200	1	200
			a	Eutroxsig	LN	MP NP		200	1	200
			b	Levothox	AF	MP NP		200	1	200
			a	LEVOXINE	RA	MP NP		200	1	200
			a	Oroxine	AS	MP NP		200	1	200

[54] Schedule 1, Part 1, entry for Lisinopril in each of the forms: Tablet 5 mg; and Tablet 10 mg

omit:

			a	Lisinopril generichealth	GQ	MP NP		30	5	30

[55] Schedule 1, Part 1, after entry for Minoxidil in the form Tablet 10 mg

insert:

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

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

(a) *omit:*

			a	Momasone	AS	MP NP	C4957 C6218 P4957	1	0	1

							C6231 C6232 C6246 C6263			

(b) *omit:*

			a	Momasone	AS	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6232	2	5	1

(c) *omit:*

			a	Momasone	AS	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6246	3	5	1

(d) *omit:*

			a	Momasone	AS	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6218 P6263	4	5	1

(e) *omit:*

			a	Momasone	AS	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6231	5	5	1

[57] Schedule 1, Part 1, entry for Naltrexone

omit from the column headed "Authorised Prescriber": **MP** *substitute:* **MP NP**

[58] Schedule 1, Part 1, entry for Nicotine

substitute:

Nicotine	Transdermal patch 17.5 mg	Transdermal	Nicotinell Step 3	ON	MP NP	C14040		28	2	28
	Transdermal patch 35 mg	Transdermal	Nicotinell Step 2	ON	MP NP	C14040		28	2	28
	Transdermal patch 39.4 mg	Transdermal	nicorette 16hr Invisipatch	JT	MP NP	C14040		28	2	28
	Transdermal patch 52.5 mg	Transdermal	Nicotinell Step 1	ON	MP NP	C5140 C14040		28	2	28

	Transdermal patch 114 mg	Transdermal		Nicabate P	GJ	MP NP	C14040		28	2	28	

[59] Schedule 1, Part 1, entry for Ofloxacin

omit from the column headed "Responsible Person": **AG** *substitute:* **VE**

[60] Schedule 1, Part 1, entry for Olanzapine in each of the forms: Tablet 2.5 mg; and Tablet 5 mg

omit:

			a	Olanzapine-DRLA	RZ	MP NP	C5856 C5869		28	5	28	

[61] Schedule 1, Part 1, entry for Olanzapine in each of the forms: Tablet 7.5 mg; and Tablet 10 mg

omit:

			a	Olanzapine-DRLA	RZ	MP NP	C5856 C5869		28	5	28	

[62] Schedule 1, Part 1, entry for Olmesartan in each of the forms: Tablet containing olmesartan medoxomil 20 mg; and Tablet containing olmesartan medoxomil 40 mg

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

			a	Olsetan	MQ	MP NP			30	5	30	

[63] Schedule 1, Part 1, entry for Omeprazole in the form Tablet 20 mg

omit from the column headed "Responsible Person" for the brand "Ozmep" (all instances): **ZP** *substitute (all instances):* **RW**

[64] Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg

(a) *omit:*

				Ondansetron ODT GH	GQ	MP NP	C5618 C10498	P5618	4	0	4	
						MP	C5743		4	0	4	C(100)

(b) *omit:*

				Ondansetron ODT GH	GQ	MP NP	C5618 C10498	P10498	10	1	10	

[65] **Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg**

(a) *omit:*

		Ondansetron ODT GH	GQ	MP NP	C5618 C10498	P5618	4	0	4	
				MP	C5743		4	0	4	C(100)

(b) *omit:*

		Ondansetron ODT GH	GQ	MP NP	C5618 C10498	P10498	10	1	10	

[66] **Schedule 1, Part 1, entry for Paracetamol in the form Tablet 665 mg (modified release)** ***[Maximum Quantity: 192; Number of Repeats: 3]***

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

	a	Parapane OSTEO	AF	MP NP	C6225 C6280	P6225	192	3	96	

[67] **Schedule 1, Part 1, entry for Paracetamol in the form Tablet 665 mg (modified release)** ***[Maximum Quantity: 192; Number of Repeats: 5]***

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

	a	Parapane OSTEO	AF	MP NP	C6225 C6280	P6280	192	5	96	

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

omit from the column headed "Responsible Person" for the brand "Refresh Night Time" (all instances): **AG** *substitute (all instances):* **VE**

[69] **Schedule 1, Part 1, entry for Paroxetine**

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

	a	Blooms The Chemist Paroxetine	BG	MP NP	C4755 C6277 C6636		30	5	30	

[70] **Schedule 1, Part 1, entry for Pembrolizumab**

insert in numerical order in the column headed "Circumstances": **C14027 C14028 C14044**

[71] **Schedule 1, Part 1, after entry for Phenoxymethylpenicillin in the form Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL *[Maximum Quantity: 2; Number of Repeats: 1]***

insert:

	Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL (s19A)	Oral		Penopen	QY	PDP		2	0	1
						MP NP		2	1	1

[72] **Schedule 1, Part 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 80 mg**

(a) *omit:*

			a	Pravastatin generichealth	GQ	MP NP		30	5	30

(b) *omit:*

			a	Pravastatin generichealth	GQ	MP	P7598	30	11	30

[73] **Schedule 1, Part 1, entry for Prednisolone with phenylephrine**

omit from the column headed "Responsible Person": **AG** *substitute:* **VE**

[74] **Schedule 1, Part 1, entry for Pregabalin in the form Capsule 25 mg**

omit:

			a	Pregabalin GH	GQ	MP NP	C4172	56	5	56

[75] **Schedule 1, Part 1, entry for Quinapril in the form Tablet 20 mg (as hydrochloride)**

omit:

			a	Quinapril generichealth	GQ	MP NP		30	5	30

[76] **Schedule 1, Part 1, entry for Ranitidine in the form Tablet 150 mg (as hydrochloride)**

(a) *omit from the column headed "Schedule Equivalent" for the brand "APO-Ranitidine":* **a**

(b) *omit:*

				a	Zantac	AS	MP NP MW			60	5	60	

[77] Schedule 1, Part 1, entry for Ranitidine in the form Tablet 300 mg (as hydrochloride)

(a) *omit from the column headed "Schedule Equivalent" for the brand "APO-Ranitidine":* **a**

(b) *omit:*

				a	Zantac	AS	MP NP			30	5	30	

[78] Schedule 1, Part 1, entry for Rasagiline

omit:

				a	Rasazil	GQ	MP NP	C5339		30	5	30	

[79] Schedule 1, Part 1, entry for Selinexor

substitute:

Selinexor	Tablet 20 mg	Oral		Xpovio	TG	MP	C13161 C14021 C14022 C14023 C14024 C14031 C14037 C14039 C14045	P14021 P14022 P14045	16	2	16	D(100)
						MP	C13161 C14021 C14022 C14023 C14024 C14031 C14037 C14039 C14045	P14023 P14024 P14037	20	2	20	D(100)
						MP	C13161 C14021 C14022 C14023 C14024 C14031 C14037 C14039 C14045	P13161 P14031 P14039	32	2	32	D(100)

[80] Schedule 1, Part 1, entry for Telmisartan in the form Tablet 80 mg

omit:

				a	Telmisartan GH	GQ	MP NP			28	5	28	

[81] Schedule 1, Part 1, entry for Telmisartan with hydrochlorothiazide in the form Tablet 40 mg-12.5 mg

omit:

	a	Telmisartan HCT GH 40/12.5	GQ	MP NP	C4374	28	5	28	

[82] Schedule 1, Part 1, entry for Telmisartan with hydrochlorothiazide in the form Tablet 80 mg-12.5 mg

omit:

	a	Telmisartan HCT GH 80/12.5	GQ	MP NP	C4374	28	5	28	

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

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

		Tenofovir Disoproxil Emtricitabine Viatris 300/200	AL	MP NP	C11143	30	2	30	
				MP NP	C6985 C6986	60	5	30	C(100)

[84] Schedule 1, Part 1, entry for Venlafaxine in the form Capsule (modified release) 37.5 mg (as hydrochloride)

omit from the column headed "Responsible Person" for the brand "Elaxine SR 37.5": **ZP** *substitute:* **RW**

[85] Schedule 1, Part 1, entry for Venlafaxine in the form Capsule (modified release) 75 mg (as hydrochloride)

omit from the column headed "Responsible Person" for the brand "Elaxine SR 75": **ZP** *substitute:* **RW**

[86] Schedule 1, Part 1, entry for Venlafaxine in the form Capsule (modified release) 150 mg (as hydrochloride)

omit from the column headed "Responsible Person" for the brand "Elaxine SR 150": **ZP** *substitute:* **RW**

[87] Schedule 1, Part 1, entry for Vinorelbine in the form Capsule 20 mg (as tartrate)

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

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

	a	Velabine	LI	MP	C4242 C4272	20	2	1	

[88] **Schedule 1, Part 1, entry for Vinorelbine in the form Capsule 30 mg (as tartrate)**

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

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

			a	Velabine	LI	MP	C4242 C4272	16	2	1

[89] **Schedule 1, Part 2, omit entry for Abatacept**

[90] **Schedule 1, Part 2, omit entry for Adalimumab**

[91] **Schedule 1, Part 2, omit entry for Ampicillin**

[92] **Schedule 1, Part 2, omit entry for Baricitinib**

[93] **Schedule 1, Part 2, omit entry for Certolizumab pegol**

[94] **Schedule 1, Part 2, omit entry for Dipyridamole with aspirin**

[95] **Schedule 1, Part 2, entry for Donepezil in each of the forms: Tablet containing donepezil hydrochloride 5 mg; and Tablet containing donepezil hydrochloride 10 mg**

omit:

			a	Donepezil-DRLA	RZ	MP	C10099 C10100	28	5	28

[96] **Schedule 1, Part 2, omit entry for Doxepin**

[97] **Schedule 1, Part 2, omit entry for Etanercept**

[98] **Schedule 1, Part 2, omit entry for Golimumab**

[99] **Schedule 1, Part 2, omit entry for Infliximab**

[100] **Schedule 1, Part 2, after entry for Insulin aspart in the form Injections (human analogue) (fast acting), pre-filled pen, 100 units per mL, 3 mL, 5**

insert:

Labetalol	Tablet containing labetalol hydrochloride 200 mg	Oral	a	Trandate	AS	MP NP		100	5	100

[101] **Schedule 1, Part 2, omit entry for Pindolol**

[102] Schedule 1, Part 2, entry for Polyvinyl alcohol

(a) *omit from the column headed "Responsible Person" for the brand "Liquifilm Tears" (all instances):* **AG** *substitute (all instances):* **VE**

(b) *omit from the column headed "Responsible Person" for the brand "PVA Tears" (all instances):* **PE** *substitute (all instances):* **VB**

[103] Schedule 1, Part 2, omit entry for Risedronic acid and calcium

[104] Schedule 1, Part 2, omit entry for Tofacitinib

[105] Schedule 1, Part 2, omit entry for Upadacitinib

[106] Schedule 3,

omit:

AG	Allergan Australia Pty Limited	85 000 612 831

[107] Schedule 3,

omit:

PE	Allergan Australia Pty Limited	85 000 612 831

[108] Schedule 3, after details relevant to Responsible Person code QY

insert:

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

[109] Schedule 3, after details relevant to Responsible Person code UR

insert:

VB	AbbVie Pty Ltd	48 156 384 262

[110] Schedule 4, Part 1, entry for Abatacept

omit:

	C12378	P12378		Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab);	Compliance with Written Authority Required procedures

				AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; AND Patient must have demonstrated 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 aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.	
	C12385	P12385		Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR	Compliance with Written Authority Required procedures

				Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.	

				If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 5 repeats. Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 5 repeats.	

[111] Schedule 4, Part 1, entry for Adalimumab

omit:

	C12354	P12354		Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:	Compliance with Written Authority Required procedures

				(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C12364	P12364		Severe active juvenile idiopathic arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine 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	Compliance with Written Authority Required procedures

				overgrowth). An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C12366	P12366		Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated 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 aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.	Compliance with Written Authority Required procedures

				The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.	
	C12391	P12391		Severe active juvenile idiopathic arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated 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 aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.	Compliance with Written Authority Required procedures

				The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.	

[112] Schedule 4, Part 1, entry for Apalutamide

insert in numerical order after existing text:

	C14034			Metastatic castration sensitive carcinoma of the prostate The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy; AND Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug. Patient must be undergoing concurrent androgen deprivation therapy.	Compliance with Authority Required procedures

[113] Schedule 4, Part 1, entry for Baricitinib

omit:

	C12354	P12354		Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021;	Compliance with Written Authority Required procedures

				AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C12366	P12366		Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR	Compliance with Written Authority Required procedures

				Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated 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 aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.	

[114] Schedule 4, Part 1, entry for Cannabidiol

insert in numerical order after existing text:

	C14047			Seizures of the Lennox-Gastaut syndrome Patient must have a diagnosis of Lennox-Gastaut syndrome confirmed by an electroencephalogram (EEG) that showed a pattern of slow (less than 3.0 hertz) spike-and-wave discharges with generalised paroxysmal fast activity (sleep recording should be obtained where it is possible); AND Patient must have (as an initiating patient)/have had (as a continuing patient) more than one type of generalised seizures; AND Patient must have had at least two drop seizures (atonic, tonic or tonic-clonic) per week that are not adequately controlled with at least two other anti-epileptic drugs prior to initiating treatment with this medicine; AND The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs. Must be treated by a neurologist if treatment is being initiated; OR Must be treated by a neurologist if treatment is being continued or re-initiated; OR Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; OR Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued. Tonic seizures must have been recorded on video-EEG or have been clearly observed and reported by a witness. Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.	Compliance with Authority Required procedures

[115] Schedule 4, Part 1, entry for Certolizumab pegol

(a) *omit:*

	C12354	P12354		Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.	Compliance with Written Authority Required procedures

				An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C12366	P12366		Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated 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 aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number	Compliance with Written Authority Required procedures

				of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.	

(b) *omit:*

	C12393	P12393		Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) - Balance of Supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) restriction to complete 24 weeks treatment, depending on the dosage regimen; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.	Compliance with Authority Required procedures

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

(a) *omit:*

	C12284			Chronic severe dry eye disease with keratitis Continuing treatment Patient must have received PBS-subsidised treatment with this drug for this condition; AND The condition must have improved to an extent that corneal fluorescein staining, using the same scale used at the time of the first authority application, shows an improvement (reduction) by at least 3 grades from baseline (the grade stated in the first authority application) - the improvement need only be demonstrated by staining once only with the first Continuing treatment authority application; AND The condition must have improved to an extent that the patient's ocular surface disease index score at the time of this	Compliance with Authority Required procedures

				authority application, has improved (reduced) by at least 30% compared to the value stated in the first authority application (i.e. baseline). Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; OR Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines. Prescribing instructions: State in the first continuing treatment authority application for this drug: (i) an improved corneal fluorescein staining grade (a numerical value that has improved by 3 grades from that provided in the first Initial 1 treatment authority application). State in all continuing treatment authority applications: (ii) the ocular surface disease index score at the time of this authority application (a numerical value that is at least 30% lower than that stated in the first Initial 1 treatment authority application).	
	C12346			Chronic severe dry eye disease with keratitis Initial treatment for up to the first 180 days of treatment Patient must have a corneal fluorescein staining (CFS) grade of 4 at treatment initiation, using at least one of: (i) the Oxford scale, (ii) the modified Oxford scale, (iii) an equivalent scale to the Oxford scale as determined by the prescriber; AND Patient must have an ocular surface disease index (OSDI) score of at least 23 at treatment initiation; AND The condition must be inadequately controlled by monotherapy with a preservative free artificial tears substitute. Patient must be undergoing simultaneous treatment with a preservative free artificial tears substitute; AND Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; OR Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines; AND Patient must not be undergoing treatment with this drug under this treatment phase beyond day 180 of treatment. Patient must be at least 18 years of age. Prescribing instruction: State in the first authority application for this drug, for the purpose of having a baseline measurement to assess response to treatment under the Continuing treatment listing, each of: (i) the qualifying corneal fluorescein staining grade (a numerical value no less than 4), (ii) the qualifying ocular surface disease index score (a numerical value no less than 23).	Compliance with Authority Required procedures

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

	C14026			Chronic severe dry eye disease with keratitis Initial treatment for up to the first 180 days of treatment Patient must have a corneal fluorescein staining (CFS) grade of 4 at treatment initiation, using at least one of: (i) the Oxford scale, (ii) the modified Oxford scale, (iii) an equivalent scale to the Oxford scale as determined by the prescriber; AND Patient must have an ocular surface disease index (OSDI) score of at least 23 at treatment initiation; AND The condition must be inadequately controlled by monotherapy with a preservative free artificial tears substitute; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be undergoing simultaneous treatment with a preservative free artificial tears substitute; AND Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; OR Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines; AND Patient must not be undergoing treatment with this drug under this treatment phase beyond day 180 of treatment.	Compliance with Authority Required procedures

				Patient must be at least 18 years of age. Prescribing instruction: State in the first authority application for this drug, for the purpose of having a baseline measurement to assess response to treatment under the Continuing treatment listing, each of: (i) the qualifying corneal fluorescein staining grade (a numerical value no less than 4), (ii) the qualifying ocular surface disease index score (a numerical value no less than 23).	
	C14032			Chronic severe dry eye disease with keratitis Continuing treatment Patient must have received PBS-subsidised treatment with this drug for this condition; AND The condition must have improved to an extent that corneal fluorescein staining, using the same scale used at the time of the first authority application, shows an improvement (reduction) by at least 3 grades from baseline (the grade stated in the first authority application) - the improvement need only be demonstrated by staining once only with the first Continuing treatment authority application; AND The condition must have improved to an extent that the patient's ocular surface disease index score at the time of this authority application, has improved (reduced) by at least 30% compared to the value stated in the first authority application (i.e. baseline); AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; OR Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines. Prescribing instructions: State in the first continuing treatment authority application for this drug: (i) an improved corneal fluorescein staining grade (a numerical value that has improved by 3 grades from that provided in the first Initial 1 treatment authority application). State in all continuing treatment authority applications: (ii) the ocular surface disease index score at the time of this authority application (a numerical value that is at least 30% lower than that stated in the first Initial 1 treatment authority application).	Compliance with Authority Required procedures

[117] Schedule 4, Part 1, omit entry for Dipyridamole with aspirin

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

omit:

	C12354	P12354		Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this	Compliance with Written Authority Required procedures

				condition 5 times. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C12359	P12359		Severe active juvenile idiopathic arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated an adequate response to treatment with this drug; AND	Compliance with Written Authority Required procedures

				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. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.	
	C12366	P12366		Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this	Compliance with Written Authority Required procedures

				condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated 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 aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.	
	C12389	P12389		Severe active juvenile idiopathic arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND	Compliance with Written Authority Required procedures

				The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine 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). An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	

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

omit:

	C12401	P12401		Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks	Compliance with Written Authority Required procedures

				of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C12468	P12468		Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated 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; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will	Compliance with Written Authority Required procedures

				not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.	

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

omit:

	C12363	P12363		Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) - Balance of Supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) restriction, with subcutaneous form restriction to complete 22 weeks initial treatment (intravenous and subcutaneous inclusive); AND The treatment must provide no more than the balance of up to 22 weeks treatment available under the - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) - subcutaneous form. Patient must be aged 18 years or older.	Compliance with Authority Required procedures
	C12378	P12378		Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; AND Patient must have demonstrated 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 aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).	Compliance with Written Authority Required procedures

				Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.	
	C12390	P12390		Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - Change of treatment due to critical shortage of tocilizumab) - subcutaneous form at weeks 6, 8, 10, 12, 14 and 16 Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must have received 2 intravenous infusions with this drug for this condition at weeks 0 and 2 under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.	Compliance with Written Authority Required procedures

				The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	

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

insert in numerical order after existing text:

	C14041	P14041		Advanced, metastatic or recurrent endometrial carcinoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR	Compliance with Authority Required procedures - Streamlined Authority Code 14041

				Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; OR Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose.	
	C14042	P14042		Advanced, metastatic or recurrent endometrial carcinoma Initial treatment Patient must have received prior treatment with platinum-based chemotherapy; AND The condition must be untreated with each of: (i) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (ii) tyrosine kinase inhibitor therapy; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation. Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 14042
	C14043	P14043		Advanced, metastatic or recurrent endometrial carcinoma Transitioning from non-PBS to PBS-subsided treatment - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023; AND The treatment must be occurring in a patient where each of the following is true: (i) the patient had received prior treatment with platinum-based chemotherapy, (ii) the patient was untreated at treatment initiation with each of: (a) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (b) tyrosine kinase inhibitor therapy, (iii) the patient's WHO performance status was no higher than 1 at treatment initiation, (iv) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (c) as monotherapy after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose, (v) disease progression has not occurred whilst on treatment.	Compliance with Authority Required procedures - Streamlined Authority Code 14043

[122] Schedule 4, Part 1, entry for Nicotine

substitute:

Nicotine	C5140			Nicotine dependence Patient must be an Aboriginal or a Torres Strait Islander person. The treatment must be the sole PBS-subsidised therapy for this condition.	
	C14040			Nicotine dependence The treatment must be as an aid to achieving abstinence from smoking; AND The treatment must not be a PBS-benefit with other non-nicotine drugs that are PBS indicated for smoking cessation; AND Patient must have indicated they are ready to cease smoking; AND Patient must not receive more than 2 x 12-week PBS-subsidised treatment courses per 12 month period. Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling	

				program or is about to enter such a program at the time PBS-subsidised treatment is initiated. Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.	

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

insert in numerical order after existing text:

	C14027			Advanced, metastatic or recurrent endometrial carcinoma Initial treatment Patient must have received prior treatment with platinum-based chemotherapy; AND The condition must be untreated with each of: (i) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (ii) tyrosine kinase inhibitor therapy; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation. Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	Compliance with Authority Required procedures - Streamlined Authority Code 14027
	C14028			Advanced, metastatic or recurrent endometrial carcinoma Transitioning from non-PBS to PBS-subsided supply - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023; AND The treatment must be occurring in a patient where each of the following is true: (i) the patient had received prior treatment with platinum-based chemotherapy, (ii) the patient was untreated at treatment initiation with each of: (a) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (b) tyrosine kinase inhibitor therapy, (iii) the patient's WHO performance status was no higher than 1 at treatment initiation, (iv) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (v) disease progression has not occurred whilst on treatment, (vi) this prescription does not extend treatment beyond 24 months from the first administered dose. Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	Compliance with Authority Required procedures - Streamlined Authority Code 14028
	C14044			Advanced, metastatic or recurrent endometrial carcinoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 14044

				Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.	

[124] Schedule 4, Part 1, omit entry for Risedronic acid and calcium

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

substitute:

Selinexor	C13161	P13161		Relapsed and/or refractory multiple myeloma Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 160 mg per week Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2022; AND The treatment must be in combination with dexamethasone; AND Patient must have progressive disease after at least four prior lines of therapy, prior to initiating non-PBS-subsidised therapy with this drug for this condition; AND Patient must have demonstrated refractory disease to prior treatments, prior to initiating non-PBS-subsidised therapy with this drug for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody; AND Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	Compliance with Authority Required procedures

	C14021	P14021		Relapsed and/or refractory multiple myeloma Initial treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week The condition must be confirmed by a histological diagnosis; AND Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND Patient must have progressive disease after at least one prior therapy; AND Patient must not have previously received this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records. Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records: (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy	Compliance with Authority Required procedures

	C14022	P14022		Relapsed and/or refractory multiple myeloma Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 80 mg, 60 mg or 40 mg per week Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023; AND Patient must have met all initial treatment PBS eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are: (a) the condition was confirmed by histological diagnosis, (b) the treatment is/was being used as part of combination therapy limited to this drug in combination with either: (i) dexamethasone, (ii) dexamethasone plus bortezomib, (c) the condition progressed (see definition of progressive disease below) after at least one prior therapy, (d) the patient had never been treated with this drug; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	Compliance with Authority Required procedures
	C14023	P14023		Relapsed and/or refractory multiple myeloma Continuing treatment - Dose requirement of 100 mg per week Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).	Compliance with Authority Required procedures

				Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	
	C14024	P14024		Relapsed and/or refractory multiple myeloma Initial treatment - Dose requirement of 100 mg per week The condition must be confirmed by a histological diagnosis; AND Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND Patient must have progressive disease after at least one prior therapy; AND Patient must not have previously received this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy	Compliance with Authority Required procedures
	C14031	P14031		Relapsed and/or refractory multiple myeloma Continuing treatment - Dose requirement of 160 mg per week Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).	Compliance with Authority Required procedures

				Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	
	C14037	P14037		Relapsed and/or refractory multiple myeloma Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 100 mg per week Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023; AND Patient must have met all initial treatment PBS eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are: (a) the condition was confirmed by histological diagnosis, (b) the treatment is/was being used as part of combination therapy limited to this drug in combination with either: (i) dexamethasone, (ii) dexamethasone plus bortezomib, (c) the condition progressed (see definition of progressive disease below) after at least one prior therapy, (d) the patient had never been treated with this drug; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	Compliance with Authority Required procedures
	C14039	P14039		Relapsed and/or refractory multiple myeloma Initial treatment - Dose requirement of 160 mg per week The condition must be confirmed by a histological diagnosis; AND Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND Patient must have progressive disease after at least one prior therapy; AND Patient must not have previously received this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other	Compliance with Authority Required procedures

				cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy	
	C14045	P14045		Relapsed and/or refractory multiple myeloma Continuing treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	Compliance with Authority Required procedures

[126] Schedule 4, Part 1, entry for Tofacitinib

omit:

	C12354	P12354		Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and	Compliance with Written Authority Required procedures

				(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C12366	P12366		Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated 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 aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least	Compliance with Written Authority Required procedures

				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 active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.	

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

omit:

	C12354	P12354		Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND	Compliance with Written Authority Required procedures

				Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C12366	P12366		Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND	Compliance with Written Authority Required procedures

				Patient must have demonstrated 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 aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.	

[128] Schedule 5, entry for Amoxicillin with clavulanic acid

substitute:

Amoxicillin with clavulanic acid	GRP-26768	Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)	Oral	AMCLAVOX DUO FORTE 875/125 APO-AMOXY/CLAV 875/125 APO-Amoxycillin and Clavulanic Acid APX-Amoxicillin/Clavulanic Acid

				AlphaClav Duo Forte AmoxyClav generichealth 875/125 Amoxyclav AN 875/125 Augmentin Duo forte Curam Duo Forte 875/125
		Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (s19A)	Oral	Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Medsurge) Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals) Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs)

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

insert:

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

[130] Schedule 5, after entry for Desvenlafaxine in the form Tablet (modified release) 50 mg (as benzoate) *[GRP-16220]*

insert:

Disopyramide	GRP-27397	Capsule 100 mg	Oral	Rythmodan
		Capsule 100 mg (s19A)	Oral	Rythmodan (Canada)

[131] Schedule 5, after entry for Lansoprazole in the form Tablet 30 mg (orally disintegrating)

insert:

Larotrectinib	GRP-27403	Oral solution 20 mg per mL (as sulfate), 50 mL, 2	Oral	VITRAKVI
		Oral solution 20 mg per mL (as sulfate), 100 mL	Oral	Vitrakvi

[132] Schedule 5, after entry for Methylprednisolone in the form Powder for injection 40 mg (as sodium succinate) with diluent

insert:

Minoxidil	GRP-27410	Tablet 10 mg	Oral	Loniten
		Tablet 10 mg (s19A)	Oral	Minoxidil 10 mg (Roma Pharmaceuticals)

[133] Schedule 5, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg *[GRP-15402]*

omit from the column headed "Brand": **ODT Ondansetron GH**

[134] Schedule 5, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg *[GRP-15983]*

omit from the column headed "Brand": **ODT Ondansetron GH**

[135] Schedule 5, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg *[GRP-16933]*

omit from the column headed "Brand": **ODT Ondansetron GH**

[136] Schedule 5, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg *[GRP-17042]*

omit from the column headed "Brand": **ODT Ondansetron GH**

[137] Schedule 5, after entry for Perindopril with indapamide in the form Tablet containing perindopril arginine 5 mg with indapamide hemihydrate 1.25 mg

insert:

Phenoxymethylpenicillin	GRP-27408	Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL	Oral	Phenoxymethylpenicillin-AFT
		Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL (s19A)	Oral	Penopen

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

insert in alphabetical order in the column headed "Brand": **Tenofovir Disoproxil Emtricitabine Viatris 300/200**