PB 67 of 2023

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 7)

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 27 July 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. 7)*.

(2) This Instrument may also be cited as PB 67 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 August 2023*	*1 August 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Acamprosate

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

			a	ACAMPROSATE VIATRIS	MQ	MP NP	C5366	180	1	180

[2] Schedule 1, Part 1, entry for Acarbose in the form Tablet 50 mg

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

			a	Acarbose Viatris	AL	MP NP		90	5	90

[3] Schedule 1, Part 1, entry for Amino acid formula with vitamins and minerals without methionine

omit:

	Oral powder 500 g (XMET Maxamum)	Oral		XMET Maxamum	SB	MP NP	C5534	8	5	1

[4] Schedule 1, Part 1, entry for Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine

omit:

	Oral powder 500 g (XMTVI Maxamum)	Oral		XMTVI Maxamum	SB	MP NP	C5542 C5560	8	5	1

[5] Schedule 1, Part 1, entry for Amino acid formula with vitamins and minerals without phenylalanine

omit:

	Sachets containing oral powder 24 g, 30 (PKU gel)	Oral		PKU gel	VF	MP NP	C4295	4	5	1

[6] Schedule 1, Part 1, entry for Amino acid formula with vitamins and minerals without phenylalanine and tyrosine

omit:

	Oral powder 500 g (XPhen, Tyr Maxamum)	Oral	XPhen, Tyr Maxamum	SB	MP NP	C5533	8	5	1	

[7] Schedule 1, Part 1, entry for Amino acid formula with vitamins and minerals without valine, leucine and isoleucine

omit:

	Oral powder 500 g (MSUD AID III)	Oral	MSUD AID III	SB	MP NP	C5571	4	5	1	

[8] Schedule 1, Part 1, entry for Atovaquone with proguanil

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

		a	AtovaquoPro Lupin 250/100	GQ	MP NP	C5981	12	0	12	

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

[9] Schedule 1, Part 1, entry for Bendamustine

substitute:

Bendamustine	Powder for injection containing bendamustine hydrochloride 25 mg	Injection	Bendamustine Sandoz	SZ	MP	C7943 C7944 C7972	See Note 3	See Note 3	1	D(100)
			Bendamustine Viatris	AF	MP	C7943 C7944 C7972	See Note 3	See Note 3	1	D(100)
			Ribomustin	JC	MP	C7943 C7944 C7972	See Note 3	See Note 3	1	D(100)
	Powder for injection containing bendamustine hydrochloride 100 mg	Injection	Bendamustine Sandoz	SZ	MP	C7943 C7944 C7972	See Note 3	See Note 3	1	D(100)
			Bendamustine Viatris	AF	MP	C7943 C7944 C7972	See Note 3	See Note 3	1	D(100)
			Ribomustin	JC	MP	C7943 C7944 C7972	See Note 3	See Note 3	1	D(100)

[10] Schedule 1, Part 1, entry for Budesonide with formoterol in the form Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses

substitute:

Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses	Inhalation by mouth	a	DuoResp Spiromax	EV	MP NP	C7979 C10121		2	5	1
					MP NP	C7979 C10121		2	5	2
		a	Rilast TURBUHALER 400/12	ZA	MP NP	C7979 C10121		2	5	1
		a	Symbicort TURBUHALER 400/12	AP	MP NP	C7979 C10121		2	5	1
		a	BiResp Spiromax	TB	MP NP	C7979 C10121		2	5	2

[11] Schedule 1, Part 1, entry for Budesonide with formoterol in the form Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses

substitute:

Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses	Inhalation by mouth	a	Rilast RAPIHALER 100/3	ZA	MP	C4397 C10482 C10538	P10482	2	2	1
					NP	C4397 C10482	P10482	2	2	1
		a	Symbicort Rapihaler 100/3	AP	MP	C4397 C10482 C10538	P10482	2	2	1
					NP	C4397 C10482	P10482	2	2	1
		a	Rilast RAPIHALER 100/3	ZA	MP	C4397 C10482 C10538	P4397 P10538	2	5	1

					NP	C4397 C10482	P4397	2	5	1
		a	Symbicort Rapihaler 100/3	AP	MP	C4397 C10482 C10538	P4397 P10538	2	5	1
					NP	C4397 C10482	P4397	2	5	1

[12] Schedule 1, Part 1, entry for Budesonide with formoterol in the form Pressurised inhalation containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses

substitute:

Pressurised inhalation containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	a	Rilast RAPIHALER 200/6	ZA	MP	C4404 C10121 C10538		2	5	1
					NP	C4404 C10121		2	5	1
		a	Symbicort Rapihaler 200/6	AP	MP	C4404 C10121 C10538		2	5	1
					NP	C4404 C10121		2	5	1

[13] Schedule 1, Part 1, entry for Cefazolin 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	Cephazolin Viatris	AL	MP NP	C5826 C5867 C5881 C5890		10	0	10

[14] Schedule 1, Part 1, entry for Certolizumab pegol in the form Injection 200 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 0]*

(a) *omit from the column headed "Circumstances":* **C11430**

(b) *insert in numerical order in the column headed "Circumstances":* **C14191**

[15] Schedule 1, Part 1, entry for Certolizumab pegol in the form Injection 200 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 2]*

(a) *omit from the column headed "Circumstances":* **C11430**

(b) *insert in numerical order in the column headed "Circumstances":* **C14191**

[16] Schedule 1, Part 1, entry for Certolizumab pegol in the form Injection 200 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C11430**

(b) *insert in numerical order in the column headed "Circumstances":* **C14191**

[17] Schedule 1, Part 1, entry for Certolizumab pegol in the form Injection 200 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 6; Number of Repeats: 0]*

(a) *omit from the column headed "Circumstances":* **C11430**

(b) *insert in numerical order in the column headed "Circumstances":* **C14191**

(c) *omit from the column headed "Purposes":* **P11430**

(d) *insert in numerical order in the column headed "Purposes":* **P14191**

[18] Schedule 1, Part 1, entry for Certolizumab pegol in the form Solution for injection 200 mg in 1 mL pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 0]*

(a) *omit from the column headed "Circumstances":* **C11430**

(b) *insert in numerical order in the column headed "Circumstances":* **C14191**

[19] Schedule 1, Part 1, entry for Certolizumab pegol in the form Solution for injection 200 mg in 1 mL pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 2]*

(a) *omit from the column headed "Circumstances":* **C11430**

(b) *insert in numerical order in the column headed "Circumstances":* **C14191**

[20] Schedule 1, Part 1, entry for Certolizumab pegol in the form Solution for injection 200 mg in 1 mL pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C11430**

(b) *insert in numerical order in the column headed "Circumstances":* **C14191**

[21] Schedule 1, Part 1, entry for Certolizumab pegol in the form Solution for injection 200 mg in 1 mL pre-filled pen *[Maximum Quantity: 6; Number of Repeats: 0]*

(a) *omit from the column headed "Circumstances":* **C11430**

(b) *insert in numerical order in the column headed "Circumstances":* **C14191**

(c) *omit from the column headed "Purposes":* **P11430**

(d) *insert in numerical order in the column headed "Purposes":* **P14191**

[22] Schedule 1, Part 1, entry for Cinacalcet in the form Tablet 90 mg (as hydrochloride) *[Maximum Quantity: 28; Number of Repeats: 5]*

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

			a	Cinacalcet Viatris	AL	MP NP	C10068		28	5	28

[23] Schedule 1, Part 1, entry for Cinacalcet in the form Tablet 90 mg (as hydrochloride) *[Maximum Quantity: 56; Number of Repeats: 5]*

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

			a	Cinacalcet Viatris	AL	MP	C10063 C10067 C10073		56	5	28	C(100)

[24] Schedule 1, Part 1, entry for Colestyramine

substitute:

Colestyramine	Sachet containing 4 g oral powder (s19A)	Oral		JAMP-Cholestyramine	DZ	MP NP			100	5	30
						MP		P6429	100	11	30
	Sachets containing 4.7 g oral powder (equivalent to 4 g colestyramine), 50	Oral		Questran Lite	GO	MP NP			2	5	1
						MP		P6429	2	11	1

[25] Schedule 1, Part 1, entry for Diroximel fumarate

omit from the column headed "Circumstances": **C13090**

[26] Schedule 1, Part 1, entry for Dosulepin in the form Tablet containing dosulepin hydrochloride 75 mg

omit:

			a	Dosulepin Mylan	MQ	MP NP			30	2	30

[27] Schedule 1, Part 1, omit entry for Efavirenz

[28] **Schedule 1, Part 1, entry for Enzalutamide in the form Capsule 40 mg *[Maximum Quantity: 112; Number of Repeats: 2]***

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

[29] **Schedule 1, Part 1, entry for Enzalutamide in the form Capsule 40 mg *[Maximum Quantity: 112; Number of Repeats: 5]***

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

(b) *insert in numerical order in the column headed "Purposes":* **P14034**

[30] **Schedule 1, Part 1, entry for Epirubicin**

omit:

	Solution for injection containing epirubicin hydrochloride 50 mg in 25 mL	Injection/intra vesical	Epirube	TB	MP			See Note 3	See Note 3	1	D(100)

[31] **Schedule 1, Part 1, entry for Eprosartan**

omit:

	Tablet 400 mg (as mesilate)	Oral	Teveten	GO	MP NP			56	5	28
					MP NP		P6328 P6329 P6332 P6351	56 CN6328 CN6329 CN6332 CN6351	5 CN6328 CN6329 CN6332 CN6351	28

[32] **Schedule 1, Part 1, after entry for Eprosartan with hydrochlorothiazide**

insert:

Eptinezumab	Solution concentrate for I.V. infusion 100 mg in 1 mL	Injection	Vyepti	LU	MP	C12029 C14189	P14189	1	0	1
					MP	C12029 C14189	P12029	1	1	1

[33] **Schedule 1, Part 1, omit entry for Ertugliflozin**

[34] **Schedule 1, Part 1, omit entry for Ertugliflozin with sitagliptin**

[35] Schedule 1, Part 1, entry for Etanercept in the form Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL

substitute:

Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection	Enbrel	PF	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	C(100)
					MP	C7289 C8638 C8662 C8692 C8718 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9410 C9429 C9473 C9487 C9502 C9554 C11107 C12164 C12260 C12261 C12262 C12265 C12266 C12287 C12289 C12327 C12434 C12457 C13532 C13533 C13535 C13537 C13538 C13539 C13540 C13542 C13593 C13598 C13646 C13647 C13707 C14108	P8638 P9064 P9386 P9388 P9410 P9429 P9473 P11107 P12164 P12260 P12261 P12262 P12265 P12266 P12287 P12289 P12327 P12434 P12457 P13532 P13533 P13535 P13537 P13538 P13539 P13540 P13542 P13593 P13598 P13646 P13647 P13707 P14108	2	3	1	
					MP	C7289 C8638 C8662 C8692 C8718 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388	P7289 P8662 P8692 P8718 P8839 P8842 P8873 P8879 P9081 P9123 P9140 P9162 P9377 P9380 P9487 P9502 P9554	2	5	1	

						C9410 C9429 C9473 C9487 C9502 C9554 C11107 C12164 C12260 C12261 C12262 C12265 C12266 C12287 C12289 C12327 C12434 C12457 C13532 C13533 C13535 C13537 C13538 C13539 C13540 C13542 C13593 C13598 C13646 C13647 C13707 C14108			
					MP	C14154 C14155	2	5	1	C(100)

[36] Schedule 1, Part 1, entry for Fluoxetine in the form Capsule 20 mg (as hydrochloride)

omit:

			a	Blooms the Chemist Fluoxetine	IB	MP NP	C4755 C6277	28	5	28

[37] Schedule 1, Part 1, entry for Fluticasone propionate with salmeterol in the form Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses

omit from the column headed "Brand": **FLUTICASONE SALMETEROL CIPHALER 250/50** *substitute:* **Fluticasone Salmeterol Ciphaler 250/50**

[38] Schedule 1, Part 1, entry for Gefitinib

(a) *omit from the column headed "Schedule Equivalent" for the brand "Cipla Gefitinib":* **a**

(b) *omit:*

			a	Iressa	AP	MP	C4473 C7447	30	3	30

[39] Schedule 1, Part 1, entry for Gentamicin

omit:

	Eye drops 3 mg (as sulfate) per	Application to		Genoptic	VE	MP	C5451 C5483	1	2	1

	mL, 5 mL	the eye				C5499					
					AO	C5476 C5477		1	2	1	

[40] Schedule 1, Part 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 3]*

(a) *omit from the column headed "Circumstances":* **C11387**

(b) *insert in numerical order in the column headed "Circumstances":* **C14190**

(c) *omit from the column headed "Purposes":* **P11387**

(d) *insert in numerical order in the column headed "Purposes":* **P14190**

[41] Schedule 1, Part 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C11387**

(b) *insert in numerical order in the column headed "Circumstances":* **C14190**

[42] Schedule 1, Part 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 3]*

(a) *omit from the column headed "Circumstances":* **C11387**

(b) *insert in numerical order in the column headed "Circumstances":* **C14190**

(c) *omit from the column headed "Purposes":* **P11387**

(d) *insert in numerical order in the column headed "Purposes":* **P14190**

[43] Schedule 1, Part 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C11387**

(b) *insert in numerical order in the column headed "Circumstances":* **C14190**

[44] Schedule 1, Part 1, entry for Hydrocortisone in the form Tablet 20 mg

substitute:

	Tablet 20 mg	Oral	a	Hydrocortisone Viatris 20	AL	MP NP			60	4	60

			a	Hysone 20	AF	MP NP			60	4	60
	Injection 100 mg (as sodium succinate) with 2 mL solvent	Injection		Solu-Cortef	PF	MP NP			2	0	1
						MP NP PDP		P6252	6	0	1

[45] Schedule 1, Part 1, entry for Hyoscine

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

			a	HYOSCINE BUTYLBROMIDE-AFT	AE	MP NP	C6207		30	3	5

[46] Schedule 1, Part 1, entry for Ketoconazole

omit:

	Shampoo 20 mg per g, 60 mL	Application		Nizoral 2%	KY	MP NP	C6434		1	1	1

[47] Schedule 1, Part 1, entry for Lanreotide in the form Injection 60 mg (as acetate) in single dose pre-filled syringe

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

			a	Mytolac	GH	MP	C4575 C7025 C7509 C7532 C9260 C9261		2	5	1	D(100)

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

[48] Schedule 1, Part 1, entry for Lanreotide in the form Injection 90 mg (as acetate) in single dose pre-filled syringe

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

			a	Mytolac	GH	MP	C4575 C7025 C7509 C7532 C9260 C9261		2	5	1	D(100)

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

[49] Schedule 1, Part 1, entry for Lanreotide in the form Injection 120 mg (as acetate) in single dose pre-filled syringe

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

			a	Mytolac	GH	MP	C4575 C7025 C7509 C7532 C9260 C9261 C10061 C10075 C10077	2	5	1	D(100)

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

[50] Schedule 1, Part 1, entry for Larotrectinib

omit:

	Oral solution 20 mg per mL (as sulfate), 100 mL	Oral		Vitrakvi	BN	MP	C12980 C12981 C12982	P12981 P12982	1	2	1
						MP	C12980 C12981 C12982	P12980	1	5	1

[51] Schedule 1, Part 1, entry for Levodopa with carbidopa

omit:

	Tablet (prolonged release) 200 mg-50 mg	Oral		Sinemet CR Prolonged-Release Tablets	OQ	MP NP	C5253	100	5	60

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

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

				Meloxicam Viatris	AL	MP NP	C4907 C4962	30	3	30

[53] Schedule 1, Part 1, entry for Mifepristone and misoprostol

substitute:

Mifepristone and misoprostol	Pack containing 1 tablet mifepristone 200 mg and 4 tablets misoprostol 200 micrograms	Oral		MS-2 Step	XH	MP NP	C14202	1	0	1

[54] Schedule 1, Part 1, entry for Morphine

omit:

	Tablet containing morphine sulfate pentahydrate 30 mg	Oral	Anamorph	RW	MP NP	C10758 C10764 C10770 C10777	P10758	10	0	20		
					PDP	C10758 C10859	P10758	10	0	20		
					MP NP	C10758 C10764 C10770 C10777	P10764 P10770 P10777	20	0	20		
					PDP	C10758 C10859	P10859	20	0	20		

[55] Schedule 1, Part 1, entry for Paclitaxel

omit:

	Solution concentrate for I.V. infusion 100 mg in 16.7 mL	Injection	Paclitaxin	TB	MP			See Note 3	See Note 3	1		D(100)
	Solution concentrate for I.V. infusion 150 mg in 25 mL	Injection	Paclitaxin	TB	MP			See Note 3	See Note 3	1		D(100)

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

omit from the column headed "Circumstances": **C13085**

[57] Schedule 1, Part 1, entry for Perindopril in the form Tablet containing perindopril arginine 2.5 mg

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

			APX-Perindopril Arginine	XT	MP NP			30	5	30		

[58] Schedule 1, Part 1, entry for Perindopril in form Tablet containing perindopril arginine 5 mg

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

			APX-Perindopril Arginine	XT	MP NP			30	5	30		

[59] Schedule 1, Part 1, entry for Perindopril in the form Tablet containing perindopril arginine 10 mg

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

			APX-Perindopril Arginine	XT	MP NP			30	5	30		

[60] **Schedule 1, Part 1, entry for Perindopril with amlodipine in the form Tablet containing 5 mg perindopril arginine with 5 mg amlodipine (as besilate)**

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

	a	APX-Perindopril Arginine/Amlodipine 5/5	XT	MP NP	C4398 C4418	30	5	30

[61] **Schedule 1, Part 1, entry for Perindopril with amlodipine in the form Tablet containing 5 mg perindopril arginine with 10 mg amlodipine (as besilate)**

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

	a	APX-Perindopril Arginine/Amlodipine 5/10	XT	MP NP	C4398 C4418	30	5	30

[62] **Schedule 1, Part 1, entry for Perindopril with amlodipine in the form Tablet containing 10 mg perindopril arginine with 5 mg amlodipine (as besilate)**

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

	a	APX-Perindopril Arginine/Amlodipine 10/5	XT	MP NP	C4398 C4418	30	5	30

[63] **Schedule 1, Part 1, entry for Perindopril with amlodipine in the form Tablet containing 10 mg perindopril arginine with 10 mg amlodipine (as besilate)**

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

	a	APX-Perindopril Arginine/Amlodipine 10/10	XT	MP NP	C4398 C4418	30	5	30

[64] **Schedule 1, Part 1, omit entry for Reteplase**

[65] **Schedule 1, Part 1, entry for Secukinumab in the form Injection 150 mg in 1 mL pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances":* **C11447**

(b) *insert in numerical order in the column headed "Circumstances":* **C14220**

[66] **Schedule 1, Part 1, entry for Secukinumab in the form Injection 150 mg in 1 mL pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* **C11447**

(b) *insert in numerical order in the column headed "Circumstances":* **C14220**

[67] **Schedule 1, Part 1, entry for Secukinumab in the form Injection 150 mg in 1 mL pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C11447**

(b) *insert in numerical order in the column headed "Circumstances":* **C14220**

[68] **Schedule 1, Part 1, entry for Secukinumab in the form Injection 150 mg in 1 mL pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* **C11447**

(b) *insert in numerical order in the column headed "Circumstances":* **C14220**

[69] **Schedule 1, Part 1, entry for Secukinumab in the form Injection 150 mg in 1 mL pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C11447**

(b) *insert in numerical order in the column headed "Circumstances":* **C14220**

[70] **Schedule 1, Part 1, entry for Secukinumab in the form Injection 150 mg in 1 mL pre-filled pen *[Maximum Quantity: 4; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances":* **C11447**

(b) *insert in numerical order in the column headed "Circumstances":* **C14220**

[71] **Schedule 1, Part 1, entry for Secukinumab in the form Injection 150 mg in 1 mL pre-filled pen *[Maximum Quantity: 5; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances":* **C11447**

(b) *insert in numerical order in the column headed "Circumstances":* **C14220**

(c) *omit from the column headed "Purposes":* **P11447**

(d) *insert in numerical order in the column headed "Purposes":* **P14220**

[72] **Schedule 1, Part 1, entry for Secukinumab in the form Injection 150 mg in 1 mL pre-filled pen *[Maximum Quantity: 8; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances":* **C11447**

(b) *insert in numerical order in the column headed "Circumstances":* **C14220**

[73] **Schedule 1, Part 1, entry for Sitagliptin**

substitute:

Sitagliptin	Tablet 25 mg	Oral	a	Januvia	XW	MP	C6346 C6363 C6376 C7505 C7541	28	5	28
						NP	C6346 C6363 C6376 C7505	28	5	28
			a	Sitagliptin Lupin	GQ	MP	C6346 C6363 C6376 C7505 C7541	28	5	28
						NP	C6346 C6363 C6376 C7505	28	5	28
			a	Sitagliptin Sandoz Pharma	SZ	MP	C6346 C6363 C6376 C7505 C7541	28	5	28
						NP	C6346 C6363 C6376 C7505	28	5	28
			a	Sitagliptin SUN	RA	MP	C6346 C6363 C6376 C7505 C7541	28	5	28
						NP	C6346 C6363 C6376 C7505	28	5	28
			a	Sitaglo	CR	MP	C6346 C6363 C6376 C7505 C7541	28	5	28
						NP	C6346 C6363 C6376 C7505	28	5	28

		a	Xelevia	XT	MP	C6346 C6363 C6376 C7505 C7541	28	5	28
					NP	C6346 C6363 C6376 C7505	28	5	28
Tablet 50 mg	Oral	a	Januvia	XW	MP	C6346 C6363 C6376 C7505 C7541	28	5	28
					NP	C6346 C6363 C6376 C7505	28	5	28
		a	Sitagliptin Lupin	GQ	MP	C6346 C6363 C6376 C7505 C7541	28	5	28
					NP	C6346 C6363 C6376 C7505	28	5	28
		a	Sitagliptin Sandoz Pharma	SZ	MP	C6346 C6363 C6376 C7505 C7541	28	5	28
					NP	C6346 C6363 C6376 C7505	28	5	28
		a	Sitagliptin SUN	RA	MP	C6346 C6363 C6376 C7505 C7541	28	5	28
					NP	C6346 C6363 C6376 C7505	28	5	28
		a	Sitaglo	CR	MP	C6346 C6363 C6376 C7505 C7541	28	5	28
					NP	C6346 C6363 C6376 C7505	28	5	28
		a	Xelevia	XT	MP	C6346 C6363 C6376 C7505	28	5	28

							C7541			
						NP	C6346 C6363 C6376 C7505	28	5	28
Tablet 100 mg	Oral	a	Januvia	XW	MP		C6346 C6363 C6376 C7505 C7541	28	5	28
						NP	C6346 C6363 C6376 C7505	28	5	28
		a	Sitagliptin Lupin	GQ	MP		C6346 C6363 C6376 C7505 C7541	28	5	28
						NP	C6346 C6363 C6376 C7505	28	5	28
		a	Sitagliptin Sandoz Pharma	SZ	MP		C6346 C6363 C6376 C7505 C7541	28	5	28
						NP	C6346 C6363 C6376 C7505	28	5	28
		a	Sitagliptin SUN	RA	MP		C6346 C6363 C6376 C7505 C7541	28	5	28
						NP	C6346 C6363 C6376 C7505	28	5	28
		a	Sitaglo	CR	MP		C6346 C6363 C6376 C7505 C7541	28	5	28
						NP	C6346 C6363 C6376 C7505	28	5	28
		a	Xelevia	XT	MP		C6346 C6363 C6376 C7505 C7541	28	5	28

	NP	C6346 C6363 C6376 C7505	28	5	28	

[74] **Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled pen *[Maximum Quantity: 4; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances":* **C14174**

(b) *insert in numerical order in the column headed "Circumstances":* **C14195**

[75] **Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled pen *[Maximum Quantity: 4; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C14174**

(b) *insert in numerical order in the column headed "Circumstances":* **C14195**

[76] **Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled pen *[Maximum Quantity: 4; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* **C14174**

(b) *insert in numerical order in the column headed "Circumstances":* **C14195**

[77] **Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled pen *[Maximum Quantity: 4; Number of Repeats: 3]***

(a) *omit from the column headed "Circumstances":* **C14174**

(b) *insert in numerical order in the column headed "Circumstances":* **C14195**

[78] **Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled pen *[Maximum Quantity: 4; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C14174**

(b) *insert in numerical order in the column headed "Circumstances":* **C14195**

(c) *omit from the column headed "Purposes":* **P14174**

(d) *insert in numerical order in the column headed "Purposes":* **P14195**

[79] **Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled pen *[Maximum Quantity: 4; Number of Repeats: 6]***

(a) *omit from the column headed "Circumstances":* **C14174**

(b) *insert in numerical order in the column headed "Circumstances":* **C14195**

[80] Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled syringe *[Maximum Quantity: 4; Number of Repeats: 0]*

(a) *omit from the column headed "Circumstances":* **C14174**

(b) *insert in numerical order in the column headed "Circumstances":* **C14195**

[81] Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled syringe *[Maximum Quantity: 4; Number of Repeats: 1]*

(a) *omit from the column headed "Circumstances":* **C14174**

(b) *insert in numerical order in the column headed "Circumstances":* **C14195**

[82] Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled syringe *[Maximum Quantity: 4; Number of Repeats: 2]*

(a) *omit from the column headed "Circumstances":* **C14174**

(b) *insert in numerical order in the column headed "Circumstances":* **C14195**

[83] Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled syringe *[Maximum Quantity: 4; Number of Repeats: 3]*

(a) *omit from the column headed "Circumstances":* **C14174**

(b) *insert in numerical order in the column headed "Circumstances":* **C14195**

[84] Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled syringe *[Maximum Quantity: 4; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C14174**

(b) *insert in numerical order in the column headed "Circumstances":* **C14195**

(c) *omit from the column headed "Purposes":* **P14174**

(d) *insert in numerical order in the column headed "Purposes":* **P14195**

[85] Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled syringe *[Maximum Quantity: 4; Number of Repeats: 6]*

(a) *omit from the column headed "Circumstances":* **C14174**

(b) *insert in numerical order in the column headed "Circumstances":* **C14195**

[86] **Schedule 1, Part 1, entry for Tofacitinib in the form Tablet 5 mg *[Maximum Quantity: 56; Number of Repeats: 3]***

(a) *insert in numerical order in the column headed "Circumstances":* **C9429 C9431**

(b) *insert in numerical order in the column headed "Circumstances":* **C14207 C14210 C14211 C14224 C14225**

(c) *insert in numerical order in the column headed "Purposes":* **P9429**

(d) *insert in numerical order in the column headed "Purposes":* **P14210 P14224 P14225**

[87] **Schedule 1, Part 1, entry for Tofacitinib in the form Tablet 5 mg *[Maximum Quantity: 56; Number of Repeats: 5]***

(a) *insert in numerical order in the column headed "Circumstances":* **C9429 C9431**

(b) *insert in numerical order in the column headed "Circumstances":* **C14207 C14210 C14211 C14224 C14225**

(c) *insert in numerical order in the column headed "Purposes":* **P9431**

(d) *insert in numerical order in the column headed "Purposes":* **P14207 P14211**

[88] **Schedule 1, Part 1, after entry for Toremifene**

insert:

Trabectedin	Powder for I.V. infusion 1 mg	Injection	Yondelis	ZL	MP	C14188 C14196 C14197	See Note 3	See Note 3	1	D(100)

[89] **Schedule 1, Part 1, entry for Tranexamic acid**

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

		a	Tranexamic Acid Lupin	GQ	MP NP		100	2	100

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

(a) *insert in numerical order in the column headed "Circumstances":* **C10434**

(b) *insert in numerical order in the column headed "Circumstances":* **C14198 C14199 C14208 C14213 C14216 C14217**

[91] **Schedule 1, Part 1, entry for Upadacitinib in the form Tablet 15 mg *[Maximum Quantity: 28; Number of Repeats: 3]***

(a) *insert in numerical order in the column headed "Circumstances":* **C10434**

(b) *insert in numerical order in the column headed "Circumstances":* **C14198 C14199 C14208 C14213 C14216 C14217**

(c) *insert in numerical order in the column headed "Purposes":* **P14208 P14213 P14216 P14217**

[92] **Schedule 1, Part 1, entry for Upadacitinib in the form Tablet 15 mg *[Maximum Quantity: 28; Number of Repeats: 4]***

(a) *insert in numerical order in the column headed "Circumstances":* **C10434**

(b) *insert in numerical order in the column headed "Circumstances":* **C14198 C14199 C14208 C14213 C14216 C14217**

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

(a) *insert in numerical order in the column headed "Circumstances":* **C10434**

(b) *insert in numerical order in the column headed "Circumstances":* **C14198 C14199 C14208 C14213 C14216 C14217**

(c) *insert in numerical order in the column headed "Purposes":* **P10434**

(d) *insert in numerical order in the column headed "Purposes":* **P14198 P14199**

[94] **Schedule 1, Part 1, entry for Varenicline**

insert as first entry:

	Tablet 0.5 mg (as tartrate) (s19A)	Oral	APO-Varenicline (Canada)	XT	MP NP	C6871		112	0	56	

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

insert as first entry:

Amino acid formula with vitamins and minerals without phenylalanine	Sachets containing oral powder 24 g, 30 (PKU gel)	Oral	PKU gel	VF	MP NP	C4295		4	5	1	

[96] **Schedule 1, Part 2, after entry for Donepezil in the form Tablet containing donepezil hydrochloride 10 mg**

insert:

Efavirenz	Tablet 200 mg	Oral	Stocrin	MK	MP NP	C4454 C4512		180	5	90	D(100)
	Tablet 600 mg	Oral	Stocrin	MK	MP NP	C4454 C4512		60	5	30	D(100)
Eprosartan	Tablet 400 mg (as mesilate)	Oral	Teveten	GO	MP NP			56	5	28	
					MP NP		P6328 P6329 P6332 P6351	56 CN6328 CN6329 CN6332 CN6351	5 CN6328 CN6329 CN6332 CN6351	28	

Ertugliflozin	Tablet 5 mg	Oral	Steglatro 5	MK	MP	C7495 C7506 C7528	28	5	28
					NP	C7495 C7506	28	5	28
	Tablet 15 mg	Oral	Steglatro 15	MK	MP	C7495 C7506 C7528	28	5	28
					NP	C7495 C7506	28	5	28
Ertugliflozin with sitagliptin	Tablet containing 5 mg ertugliflozin with 100 mg sitagliptin	Oral	Steglujan 5/100	MK	MP	C7524 C7556	28	5	28
					NP	C7556	28	5	28
	Tablet containing 15 mg ertugliflozin with 100 mg sitagliptin	Oral	Steglujan 15/100	MK	MP	C7524 C7556	28	5	28
					NP	C7556	28	5	28

[97] Schedule 1, Part 2, after entry for Galantamine in the form Capsule (prolonged release) 24 mg (as hydrobromide)

insert:

Gentamicin	Eye drops 3 mg (as sulfate) per mL, 5 mL	Application to the eye	Genoptic	VE	MP	C5451 C5483 C5499	1	2	1
					AO	C5476 C5477	1	2	1

[98] 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:

Ketoconazole	Shampoo 20 mg per g, 60 mL	Application	Nizoral 2%	KY	MP NP	C6434	1	1	1

[99] Schedule 1, Part 2, omit entry for Roxithromycin

[100] Schedule 3, after details relevant to Responsible Person code ZE

insert:

ZL	Specialised Therapeutics Pharma Pty Ltd	77 609 261 430

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

omit:

	C11526			Severe active juvenile idiopathic arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; 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. An adequate response to treatment is defined as: (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, 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). Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. 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 12 months 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.	Compliance with Authority Required procedures - Streamlined Authority Code 11526

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

(a) *omit:*

	C11430	P11430		Non-radiographic axial spondyloarthritis Initial treatment - Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with biological medicines more than three times for this PBS-indication during the current treatment cycle; AND	Compliance with Authority Required procedures

				Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The following must be provided at the time of application and documented in the patient's medical records: (a) the BASDAI score; and (b) the C-reactive protein (CRP) level.	

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

	C14191	P14191		Non-radiographic axial spondyloarthritis Initial treatment - Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:	Compliance with Authority Required procedures

				(a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The following must be provided at the time of application and documented in the patient's medical records: (a) the BASDAI score; and (b) the C-reactive protein (CRP) level.	

[103] Schedule 4, Part 1, entry for Diroximel fumarate

omit:

	C13090			Multiple sclerosis Grandfather treatment Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2022; AND The condition must be/have previously been diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of at least one of the brain/spinal cord; OR The condition must be/have previously been diagnosed as clinically definite relapsing-remitting multiple sclerosis supported by written certification, which is documented in the patient's medical records, from a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support); AND Patient must not show continuing progression of disability while on treatment with this drug. Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 13090

[104] Schedule 4, Part 1, entry for Enzalutamide

insert in numerical order after existing text:

	C14034	P14034		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

[105] Schedule 4, Part 1, after entry for Eprosartan with hydrochlorothiazide

insert:

Eptinezumab	C12029	P12029		Chronic migraine Continuing treatment Must be treated by a specialist neurologist or in consultation with a specialist neurologist; AND Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of migraine days per month; AND Patient must continue to be appropriately managed for medication overuse headache. Patient must have the number of migraine days per month documented in their medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 12029
	C14189	P14189		Chronic migraine Initial treatment Must be treated by a neurologist; AND Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication. Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition; AND Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition; AND Patient must be appropriately managed by their practitioner for medication overuse headache, prior to initiation of treatment with this drug. Patient must be at least 18 years of age. Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate. Patient must have the number of migraine days per month documented in their medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 14189

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

(a) *omit:*

	C11387	P11387		Non-radiographic axial spondyloarthritis Initial treatment - Initial 2 (Change or re-commencement of treatment after a break of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with biological medicines more than three times for this PBS-indication during the current treatment cycle; AND The treatment must not exceed a maximum of 16 weeks with this drug under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR	Compliance with Authority Required procedures

				Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The following must be provided at the time of application and documented in the patient's medical records: (a) the BASDAI score; and (b) the C-reactive protein (CRP) level.	

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

	C14190	P14190		Non-radiographic axial spondyloarthritis Initial treatment - Initial 2 (Change or re-commencement of treatment after a break of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle; AND The treatment must not exceed a maximum of 16 weeks with this drug under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a	Compliance with Authority Required procedures

				minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The following must be provided at the time of application and documented in the patient's medical records: (a) the BASDAI score; and (b) the C-reactive protein (CRP) level.	

[107] Schedule 4, Part 1, entry for Mifepristone and misoprostol

substitute:

Mifepristone and misoprostol	C14202			Termination of an intra-uterine pregnancy The condition must be an intra-uterine pregnancy of up to 63 days of gestation.	Compliance with Authority Required procedures - Streamlined Authority Code 14202

[108] Schedule 4, Part 1, entry for Morphine

(a) *omit:*

	C10758	P10758		Severe pain The treatment must be for short term therapy of acute severe pain; AND Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.	

(b) *omit from the column headed "Purposes Code" for circumstances code "C10859":* **P10859**

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

omit:

	C13085			Locally advanced or metastatic breast cancer Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2022; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND Patient must have been untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy at the time non-PBS supply was initiated; OR Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND	Compliance with Authority Required procedures

				The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time non-PBS supply was initiated; AND The treatment must be in combination with fulvestrant only, where at the time non-PBS supply was initiated, the patient had recurrent/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease; AND The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy. Patient must not be premenopausal.	

[110] Schedule 4, Part 1, omit entry for Reteplase

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

(a) *omit:*

	C11447	P11447		Non-radiographic axial spondyloarthritis Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with biological medicines more than three times for this PBS-indication during the current treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle; AND Patient must not receive more than 20 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The following must be provided at the time of application and documented in the patient's medical records: (a) the BASDAI score; and (b) the C-reactive protein (CRP) level.	Compliance with Authority Required procedures

				The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter. State in the application whether a loading dose regimen is intended or not. Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing. Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.	

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

	C14220	P14220		Non-radiographic axial spondyloarthritis Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle; AND Patient must not receive more than 20 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The following must be provided at the time of application and documented in the patient's medical records: (a) the BASDAI score; and (b) the C-reactive protein (CRP) level. The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter. State in the application whether a loading dose regimen is intended or not. Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1,	Compliance with Authority Required procedures

				2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing. Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.	

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

(a) *omit:*

	C14174	P14174		Active giant cell arteritis Initial treatment Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis. Patient must have clinical symptoms of active giant cell arteritis in the absence of any other identifiable cause; AND Patient must have an ESR equal to or greater than 30 mm/hour within the past 6 weeks; OR Patient must have a CRP equal to or greater than 10 mg/L within the past 6 weeks; OR Patient must have active giant cell arteritis confirmed by positive temporal artery biopsy or imaging; AND Patient must have had a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis; AND Patient must have had temporal artery biopsy revealing features of giant cell arteritis at diagnosis; OR Patient must have had evidence of large-vessel vasculitis by magnetic resonance (MR) or computed tomography (CT) angiography or PET/CT; OR Patient must have had evidence of positive temporal artery halo sign by ultrasound (US) at diagnosis; AND The treatment must be in combination with a tapering course of corticosteroids; AND The treatment must not exceed 52 weeks in total including initial and continuing applications. Patient must be aged 50 years or older. Clinical symptoms of giant cell arteritis at diagnosis include unequivocal cranial symptoms of giant cell arteritis (new onset localized headache, scalp tenderness, temporal artery tenderness or decreased pulsation, ischemia related vision loss, or otherwise unexplained mouth or jaw pain upon mastication); or symptoms of polymyalgia rheumatica, defined as shoulder and/or hip girdle pain associated with inflammatory morning stiffness. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS and must include: (a) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has active giant cell arteritis including pathology reports outlining the patient's ESR or CRP levels within the last 6 weeks, or positive temporal artery biopsy or imaging; and (b) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has been diagnosed with giant cell arteritis with a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Written Authority Required procedures

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

	C14195	P14195		Active giant cell arteritis Initial treatment Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis. Patient must have clinical symptoms of active giant cell arteritis in the absence of any other identifiable cause; AND Patient must have an ESR equal to or greater than 30 mm/hour within the past 6 weeks; OR Patient must have a CRP equal to or greater than 10 mg/L within the past 6 weeks; OR Patient must have active giant cell arteritis confirmed by positive temporal artery biopsy or imaging; AND Patient must have had a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis; AND Patient must have had temporal artery biopsy revealing features of giant cell arteritis at diagnosis; OR Patient must have had evidence of large-vessel vasculitis by magnetic resonance (MR) or computed tomography (CT) angiography or PET/CT at diagnosis; OR Patient must have had evidence of positive temporal artery halo sign by ultrasound (US) at diagnosis; AND The treatment must be in combination with a tapering course of corticosteroids; AND The treatment must not exceed 52 weeks in total including initial and continuing applications. Patient must be aged 50 years or older. Clinical symptoms of giant cell arteritis at diagnosis include unequivocal cranial symptoms of giant cell arteritis (new onset localized headache, scalp tenderness, temporal artery tenderness or decreased pulsation, ischemia related vision loss, or otherwise unexplained mouth or jaw pain upon mastication); or symptoms of polymyalgia rheumatica, defined as shoulder and/or hip girdle pain associated with inflammatory morning stiffness. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS and must include: (a) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has active giant cell arteritis including pathology reports outlining the patient's ESR or CRP levels within the last 6 weeks, or positive temporal artery biopsy or imaging; and (b) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has been diagnosed with giant cell arteritis with a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Written Authority Required procedures

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

(a) *insert after entry for Circumstances Code "C9064":*

	C9429	P9429		Ankylosing spondylitis Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) -	Compliance with Authority Required procedures

				balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	
	C9431	P9431		Ankylosing spondylitis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	Compliance with Authority Required procedures

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

	C14207	P14207		Ankylosing spondylitis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2023; AND Patient must have had at least 2 of the following prior to commencing non-PBS-subsidised treatment: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.	Compliance with Written Authority Required procedures

				If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response to NSAIDs and must have been demonstrated prior to initiation of non-PBS subsidised treatment with this biological medicine for this condition: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must have been determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. If the above requirement to demonstrate an elevated ESR or CRP could not be met, the application must state the reason this criterion could not be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion 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 these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. 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.	
	C14210	P14210		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	Compliance with Written Authority Required procedures

				The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment. 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. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 4 weeks old at the time of application. 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.	
	C14211	P14211		Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline.	Compliance with Written Authority Required procedures

				Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 4 weeks old at the time of application. 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 these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. 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.	
	C14224	P14224		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial	Compliance with Written Authority Required procedures

				application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion 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 these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. 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.	
	C14225	P14225		Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include:	Compliance with Written Authority Required procedures

				(a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a BASDAI score. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion 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 these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. 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.	

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

insert:

Trabectedin	C14188			Advanced (unresectable and/or metastatic) leiomyosarcoma or liposarcoma Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements Patient must have been receiving treatment with this drug for this condition prior to 1 August 2023; AND Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time non-PBS supply was initiated; AND Patient must have received chemotherapy treatment including an anthracycline, prior to initiating non-PBS-subsidised treatment; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must be one of the following subtypes for patients with liposarcoma: (i) dedifferentiated, (ii) myxoid, (iii) round-cell, (iv) pleomorphic. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.	Compliance with Authority Required procedures - Streamlined Authority Code 14188
	C14196			Advanced (unresectable and/or metastatic) leiomyosarcoma or liposarcoma Initial treatment Patient must have an ECOG performance status of 2 or less; AND Patient must have received prior chemotherapy treatment including an anthracycline; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must be one of the following subtypes for patients with liposarcoma: (i) dedifferentiated, (ii) myxoid, (iii) round-cell, (iv) pleomorphic. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.	Compliance with Authority Required procedures - Streamlined Authority Code 14196
	C14197			Advanced (unresectable and/or metastatic) leiomyosarcoma or liposarcoma 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 treatment with this drug for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority

				The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.	Code 14197

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

(a) *insert after entry for Circumstances Code "C10356":*

	C10434	P10434		Non-radiographic axial spondyloarthritis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.	Compliance with Authority Required procedures

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

	C14198	P14198		Non-radiographic axial spondyloarthritis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have commenced treatment with this biological medicine for this condition prior to 1 August 2023; AND The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.	Compliance with Written Authority Required procedures

				If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The baseline BASDAI score and CRP level must also be documented in the patient's medical records.	
	C14199	P14199		Non-radiographic axial spondyloarthritis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug for this condition; AND The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction. The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.	Compliance with Authority Required procedures
	C14208	P14208		Non-radiographic axial spondyloarthritis Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment	Compliance with Authority Required procedures

				cycle; AND The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle; AND The treatment must not exceed a maximum of 16 weeks with this drug under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The following must be provided at the time of application and documented in the patient's medical records: (a) the BASDAI score; and (b) the C-reactive protein (CRP) level.	
	C14213	P14213		Non-radiographic axial spondyloarthritis Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND	Compliance with Authority Required procedures

				The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND The treatment must not exceed a maximum of 16 weeks with this drug under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The following must be provided at the time of application and documented in the patient's medical records: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.	
	C14216	P14216		Non-radiographic axial spondyloarthritis Initial treatment - Initial 1 (New patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND The treatment must not exceed a maximum of 16 weeks with this drug under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent	Compliance with Written Authority Required procedures

				treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The baseline BASDAI score and CRP level must also be documented in the patient's medical records.	
	C14217	P14217		Non-radiographic axial spondyloarthritis Initial 1 (New patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.	Compliance with Authority Required procedures

[116] Schedule 5, after entry for Clopidogrel

insert:

Colestyramine	GRP-27566	Sachet containing 4 g oral powder (s19A)	Oral	JAMP-Cholestyramine
		Sachets containing 4.7 g oral powder (equivalent to 4 g colestyramine), 50	Oral	Questran Lite

[117] Schedule 5, omit entry for Larotrectinib

[118] **Schedule 5, omit entry for Levodopa with carbidopa**

[119] **Schedule 5, entry for Meloxicam in the form Tablet 15 mg *[GRP-15468]***

insert in alphabetical order in the column headed "Brand": **Meloxicam Viatris**

[120] **Schedule 5, entry for Perindopril in the form Tablet containing perindopril arginine 5 mg *[GRP-15442]***

insert in alphabetical order in the column headed "Brand": **APX-Perindopril Arginine**

[121] **Schedule 5, entry for Perindopril in the form Tablet containing perindopril arginine 10 mg *[GRP-15525]***

insert in alphabetical order in the column headed "Brand": **APX-Perindopril Arginine**

[122] **Schedule 5, entry for Perindopril in the form Tablet containing perindopril arginine 2.5 mg *[GRP-15965]***

insert in alphabetical order in the column headed "Brand": **APX-Perindopril Arginine**