PB 34 of 2023

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 4)

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 April 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. 4)*.

(2) This Instrument may also be cited as PB 34 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 May 2023*	*1 May 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Abiraterone in each of the forms: Tablet containing abiraterone acetate 250 mg; and Tablet containing abiraterone acetate 500 mg

omit from the column headed "Circumstances": **C12700** *substitute:* **C13945**

[2] Schedule 1, Part 1, after entry for Abiraterone in the form Tablet containing abiraterone acetate 500 mg

insert:

Abiraterone and methylprednisolone	Pack containing 120 tablets abiraterone acetate 125 mg and 60 tablets methylprednisolone 4 mg	Oral	Yonsa Mpred	RA	MP	C13992	1	2	1

[3] Schedule 1, Part 1, after entry for Artemether with lumefantrine in the form Tablet 20 mg-120 mg

insert:

Asciminib	Tablet 20 mg	Oral	Scemblix	NV	MP	C13923 C13950	60	5	60
	Tablet 40 mg	Oral	Scemblix	NV	MP	C13923 C13925 C13950 C14008 P13923 P13950	60	5	60
					MP	C13923 C13925 C13950 C14008 P13925 P14008	300	5	60

[4] Schedule 1, Part 1, entry for Budesonide in the form Tablet 500 micrograms (orally disintegrating)

(a) *omit from the column headed "Circumstances":* **C12837 C12909**

(b) *insert in numerical order in the column headed "Circumstances":* **C13968**

[5] Schedule 1, Part 1, entry for Budesonide in the form Tablet 1 mg (orally disintegrating) ***[Maximum Quantity: 60; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C12837 C12909**

(b) *insert in numerical order in the column headed "Circumstances":* **C13968**

(c) *omit from the column headed "Purposes":* **P12837 P12909**

(d) *insert in numerical order in the column headed "Purposes":* **P13968**

[6] **Schedule 1, Part 1, entry for Budesonide in the form Tablet 1 mg (orally disintegrating) *[Maximum Quantity: 90; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C12837 C12909**

(b) *insert in numerical order in the column headed "Circumstances":* **C13968**

[7] **Schedule 1, Part 1, after entry for Budesonide with formoterol in the form Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses *[Maximum Quantity: 1; Number of Repeats: 5]***

insert:

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	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

[8] **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, 2**

omit:

		a	Symbicort Turbuhaler 400/12	AP	MP NP	C7979 C10121	1	5	1

[9] **Schedule 1, Part 1, entry for Daratumumab in the form Solution for subcutaneous injection containing daratumumab 1800 mg in 15 mL *[Maximum Quantity: 1; Number of Repeats: 4]***

(a) *omit from the column headed "Circumstances":* **C13744 C13751**

(b) *insert in numerical order in the column headed "Circumstances":* **C13944 C14015**

[10] **Schedule 1, Part 1, entry for Daratumumab in the form Solution for subcutaneous injection containing daratumumab 1800 mg in 15 mL *[Maximum Quantity: 1; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C13744 C13751**

(b) *insert in numerical order in the column headed "Circumstances":* **C13944 C14015**

[11] **Schedule 1, Part 1, entry for Daratumumab in the form Solution for subcutaneous injection containing daratumumab 1800 mg in 15 mL *[Maximum Quantity: 1; Number of Repeats: 7]***

(a) *omit from the column headed "Circumstances":* **C13744 C13751**

(b) *insert in numerical order in the column headed "Circumstances":* **C13944 C14015**

[12] **Schedule 1, Part 1, entry for Daratumumab in the form Solution for subcutaneous injection containing daratumumab 1800 mg in 15 mL *[Maximum Quantity: 1; Number of Repeats: 8]***

(a) *omit from the column headed "Circumstances":* **C13744 C13751**

(b) *insert in numerical order in the column headed "Circumstances":* **C13944 C14015**

[13] **Schedule 1, Part 1, entry for Daratumumab in the form Solution for subcutaneous injection containing daratumumab 1800 mg in 15 mL *[Maximum Quantity: 1; Number of Repeats: 15]***

(a) *omit from the column headed "Circumstances":* **C13744 C13751**

(b) *insert in numerical order in the column headed "Circumstances":* **C13944 C14015**

(c) *omit from the column headed "Purposes":* **P13744 P13751** *substitute:* **P13944 P14015**

[14] **Schedule 1, Part 1, entry for Donepezil**

substitute:

Donepezil	Tablet containing donepezil hydrochloride 5 mg	Oral	a	APO-Donepezil	TX	MP	C13938 C13940 C13941	28	5	28
						NP	C13938	28	5	28
			a	Arazil	AF	MP	C13938 C13940 C13941	28	5	28
						NP	C13938	28	5	28
			a	Aricept	PF	MP	C13938 C13940 C13941	28	5	28
						NP	C13938	28	5	28
			a	Aridon 5	RW	MP	C13938 C13940 C13941	28	5	28
						NP	C13938	28	5	28

		a	Aridon APN 5	RF	MP	C13938 C13940 C13941	28	5	28
					NP	C13938	28	5	28
		a	Donepezil GH	HQ	MP	C13938 C13940 C13941	28	5	28
					NP	C13938	28	5	28
		a	Donepezil Sandoz	SZ	MP	C13938 C13940 C13941	28	5	28
					NP	C13938	28	5	28
		a	Donepezil-DRLA	RZ	MP	C13938 C13940 C13941	28	5	28
					NP	C13938	28	5	28
		a	NOUMED DONEPEZIL	VO	MP	C13938 C13940 C13941	28	5	28
					NP	C13938	28	5	28
Tablet containing donepezil hydrochloride 10 mg	Oral	a	APO-Donepezil	TX	MP	C13938 C13940 C13941	28	5	28
					NP	C13938	28	5	28
		a	Arazil	AF	MP	C13938 C13940 C13941	28	5	28
					NP	C13938	28	5	28
		a	Aricept	PF	MP	C13938 C13940 C13941	28	5	28
					NP	C13938	28	5	28
		a	Aridon 10	RW	MP	C13938 C13940 C13941	28	5	28
					NP	C13938	28	5	28

			a	Aridon APN 10	RF	MP	C13938 C13940 C13941		28	5	28	
						NP	C13938		28	5	28	
			a	Donepezil GH	HQ	MP	C13938 C13940 C13941		28	5	28	
						NP	C13938		28	5	28	
			a	Donepezil Sandoz	SZ	MP	C13938 C13940 C13941		28	5	28	
						NP	C13938		28	5	28	
			a	Donepezil-DRLA	RZ	MP	C13938 C13940 C13941		28	5	28	
						NP	C13938		28	5	28	
			a	NOUMED DONEPEZIL	VO	MP	C13938 C13940 C13941		28	5	28	
						NP	C13938		28	5	28	

[15] Schedule 1, Part 1, entry for Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor

insert as first entry:

	Pack containing 56 tablets elexacaftor 50 mg with tezacaftor 25 mg and with ivacaftor 37.5 mg and 28 tablets ivacaftor 75 mg	Oral		Trikafta	VR	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

[16] Schedule 1, Part 1, entry for Fluticasone propionate

substitute:

Fluticasone propionate	Pressurised inhalation containing fluticasone propionate 50 micrograms per dose, 120 doses (CFC-free formulation)	Inhalation by mouth	a	Axotide Junior	TX	MP NP	C13917		1	5	1	
			a	Flixotide Junior	GK	MP NP	C13917		1	5	1	

Pressurised inhalation containing fluticasone propionate 125 micrograms per dose, 120 doses (CFC-free formulation)	Inhalation by mouth	a	Axotide	TX	MP NP	1	5	1
		a	Flixotide	GK	MP NP	1	5	1
		a	Fluticasone Cipla Inhaler	LR	MP NP	1	5	1
Pressurised inhalation containing fluticasone propionate 250 micrograms per dose, 120 doses (CFC-free formulation)	Inhalation by mouth	a	Axotide	TX	MP NP	1	1	1
		a	Flixotide	GK	MP NP	1	1	1
		a	Fluticasone Cipla Inhaler	LR	MP NP	1	1	1
Powder for oral inhalation in breath actuated device containing fluticasone propionate 100 micrograms per dose, 60 doses	Inhalation by mouth	a	Axotide Junior Accuhaler	TX	MP NP	1	5	1
		a	Flixotide Junior Accuhaler	GK	MP NP	1	5	1
Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms per dose, 60 doses	Inhalation by mouth	a	Axotide Accuhaler	TX	MP NP	1	5	1
		a	Flixotide Accuhaler	GK	MP NP	1	5	1
Powder for oral inhalation in breath actuated device containing fluticasone propionate 500 micrograms per dose, 60 doses	Inhalation by mouth		Flixotide Accuhaler	GK	MP NP	1	1	1

[17] Schedule 1, Part 1, entry for Fluticasone propionate with salmeterol

substitute:

Fluticasone propionate with salmeterol	Pressurised inhalation containing fluticasone propionate 50 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation)	Inhalation by mouth	a	PAVTIDE MDI 50/25	TX	MP NP	C4930	1	5	1
			a	Seretide MDI 50/25	GK	MP NP	C4930	1	5	1
	Pressurised inhalation containing fluticasone propionate 125 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation)	Inhalation by mouth	a	Evocair MDI	AF	MP NP	C4930	1	5	1
			a	Fluticasone + Salmeterol Cipla 125/25	LR	MP NP	C4930	1	5	1
			a	Pavtide	TX	MP NP	C4930	1	5	1
			a	SalplusF Inhaler 125/25	SZ	MP NP	C4930	1	5	1
			a	Seretide MDI 125/25	GK	MP NP	C4930	1	5	1
			a	Seroflo 125/25	YC	MP NP	C4930	1	5	1
	Pressurised inhalation containing fluticasone propionate 250 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation)	Inhalation by mouth	a	Evocair MDI	AF	MP NP	C4930 C10121	1	5	1
			a	Fluticasone + Salmeterol Cipla 250/25	LR	MP NP	C4930 C10121	1	5	1

		a	Pavtide	TX	MP NP	C4930 C10121	1	5	1
		a	SalplusF Inhaler 250/25	SZ	MP NP	C4930 C10121	1	5	1
		a	Seretide MDI 250/25	GK	MP NP	C4930 C10121	1	5	1
		a	Seroflo 250/25	YC	MP NP	C4930 C10121	1	5	1
Powder for oral inhalation in breath actuated device containing fluticasone propionate 100 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses	Inhalation by mouth	a	PAVTIDE ACCUHALER 100/50	TX	MP NP	C4930	1	5	1
		a	Seretide Accuhaler 100/50	GK	MP NP	C4930	1	5	1
Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses	Inhalation by mouth	a	FLUTICASONE SALMETEROL CIPHALER 250/50	LR	MP NP	C4930	1	5	1
		a	PAVTIDE ACCUHALER 250/50	TX	MP NP	C4930	1	5	1
		a	Seretide Accuhaler 250/50	GK	MP NP	C4930	1	5	1
Powder for oral inhalation in breath actuated device containing fluticasone propionate 500 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses	Inhalation by mouth	a	PAVTIDE ACCUHALER 500/50	TX	MP NP	C4930 C10121	1	5	1
		a	Seretide Accuhaler 500/50	GK	MP NP	C4930 C10121	1	5	1

[18] Schedule 1, Part 1, entry for Galantamine

substitute:

Galantamine	Capsule (prolonged release) 8 mg (as hydrobromide)	Oral	a	APO-Galantamine MR	TX	MP	C13938 C13940 C13941	28	5	28
						NP	C13938	28	5	28
			a	Galantyl	AF	MP	C13938 C13940 C13941	28	5	28
						NP	C13938	28	5	28
			a	Gamine XR	RW	MP	C13938 C13940 C13941	28	5	28
						NP	C13938	28	5	28
			a	Reminyl	JC	MP	C13938 C13940 C13941	28	5	28
						NP	C13938	28	5	28
	Capsule (prolonged release) 16 mg (as hydrobromide)	Oral	a	APO-Galantamine MR	TX	MP	C13938 C13940 C13941	28	5	28
						NP	C13938	28	5	28
			a	Galantyl	AF	MP	C13938 C13940 C13941	28	5	28
						NP	C13938	28	5	28
			a	Gamine XR	RW	MP	C13938 C13940 C13941	28	5	28
						NP	C13938	28	5	28
			a	Reminyl	JC	MP	C13938 C13940 C13941	28	5	28
						NP	C13938	28	5	28

	Capsule (prolonged release) 24 mg (as hydrobromide)	Oral	a	APO-Galantamine MR	TX	MP	C13938 C13940 C13941		28	5	28
						NP	C13938		28	5	28
			a	Galantyl	AF	MP	C13938 C13940 C13941		28	5	28
						NP	C13938		28	5	28
			a	Gamine XR	RW	MP	C13938 C13940 C13941		28	5	28
						NP	C13938		28	5	28
			a	Reminyl	JC	MP	C13938 C13940 C13941		28	5	28
						NP	C13938		28	5	28

[19] Schedule 1, Part 1, entry for Glycomacropeptide formula with long chain polyunsaturated fatty acids and docosahexaenoic acid and low in phenylalanine

insert as first entry:

	Oral liquid 237 mL, 15 (PKU Sphere Liquid)	Oral	PKU Sphere Liquid	VF	MP NP	C4295		8	5	1

[20] Schedule 1, Part 1, entry for Ipilimumab in the form Injection concentrate for I.V. infusion 50 mg in 10 mL

omit from the column headed "Circumstances": **C11394**

[21] Schedule 1, Part 1, entry for Lenvatinib

substitute:

Lenvatinib	Capsule 4 mg (as mesilate)	Oral	Lenvima	EI	MP	C6578 C6604 C8584 C11168 C13921 C13972 C14007	P6578 P6604	30	2	30
					MP	C6578 C6604 C8584 C11168 C13921 C13972	P13921 P13972 P14007	60	2	30

							C14007				
						MP	C6578 C6604 C8584 C11168 C13921 C13972 C14007	P8584 P11168	90	2	30
	Capsule 10 mg (as mesilate)	Oral		Lenvima	EI	MP	C6578 C6604 C13921 C13972 C14007		60	2	30

[22] Schedule 1, Part 1, entry for Levodopa with carbidopa and entacapone in each of the forms: Tablet 50 mg-12.5 mg (as monohydrate)-200 mg; Tablet 75 mg-18.75 mg (as monohydrate)-200 mg; Tablet 100 mg-25 mg (as monohydrate)-200 mg; Tablet 125 mg-31.25 mg (as monohydrate)-200 mg; Tablet 150 mg-37.5 mg (as monohydrate)-200 mg; and Tablet 200 mg-50 mg (as monohydrate)-200 mg

omit:

			a	TRIDOPA	TD	MP NP	C5212 C5288		200	4	100

[23] Schedule 1, Part 1, entry for Memantine

substitute:

Memantine	Tablet containing memantine hydrochloride 10 mg	Oral	a	APO-Memantine	TX	MP	C13936 C13966 C14000		56	5	56
						NP	C13966		56	5	56
			a	Ebixa	LU	MP	C13936 C13966 C14000		56	5	56
						NP	C13966		56	5	56
			a	Memantine generichealth	GQ	MP	C13936 C13966 C14000		56	5	56
						NP	C13966		56	5	56
			a	Memanxa	RW	MP	C13936 C13966 C14000		56	5	56
						NP	C13966		56	5	56
	Tablet containing memantine	Oral	a	APO-Memantine	TX	MP	C13936 C13966		28	5	28

	hydrochloride 20 mg					C14000			
					NP	C13966	28	5	28
		a	Ebixa	LU	MP	C13936 C13966 C14000	28	5	28
					NP	C13966	28	5	28
		a	Memantine generichealth	GQ	MP	C13936 C13966 C14000	28	5	28
					NP	C13966	28	5	28

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

omit from the column headed "Circumstances" (all instances): **C10719** *substitute (all instances):* **C13922**

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

substitute:

Naltrexone	Tablet containing naltrexone hydrochloride 50 mg	Oral	Naltrexone GH	GQ	MP	C13967	30	1	30

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

omit from the column headed "Circumstances": **C13420**

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

(a) *omit from the column headed "Circumstances":* **C8573**

(b) *omit from the column headed "Circumstances":* **C11469**

(c) *insert in numerical order in the column headed "Circumstances":* **C14001**

[28] Schedule 1, Part 1, entry for Norethisterone with ethinylestradiol in the form Pack containing 21 tablets 1 mg-35 micrograms and 7 inert tablets

(a) *omit:*

				a	Brevinor-1	PF	MP NP			4	2	4

(b) *omit from the column headed "Schedule Equivalent" for the brand "Norimin-1 28 Day":* **a**

[29] Schedule 1, Part 1, entry for Olaparib in the form Tablet 100 mg *[Maximum Quantity: 112; Number of Repeats: 2]*

(a) *omit from the column headed "Circumstances":* **C12589**

(b) *omit from the column headed "Purposes":* **P12589**

[30] Schedule 1, Part 1, entry for Olaparib in the form Tablet 100 mg *[Maximum Quantity: 112; Number of Repeats: 5]*

omit from the column headed "Circumstances": **C12589**

[31] Schedule 1, Part 1, entry for Olaparib in the form Tablet 150 mg *[Maximum Quantity: 112; Number of Repeats: 2]*

(a) *omit from the column headed "Circumstances":* **C12589**

(b) *omit from the column headed "Purposes":* **P12589**

[32] Schedule 1, Part 1, entry for Olaparib in the form Tablet 150 mg *[Maximum Quantity: 112; Number of Repeats: 5]*

omit from the column headed "Circumstances": **C12589**

[33] Schedule 1, Part 1, entry for Oxycodone in the form Capsule containing oxycodone hydrochloride 5 mg

substitute:

Oxycodone	Capsule containing oxycodone hydrochloride 5 mg	Oral		OxyNorm	MF	PDP	C10766 C10768	P10766	10	0	10
						MP NP	C10764 C10766 C10771 C10772	P10766	10	0	10
						PDP	C10766 C10768	P10768	20	0	20
						MP NP	C10764 C10766 C10771 C10772	P10764 P10771 P10772	20	0	20

[34] Schedule 1, Part 1, entry for Oxycodone in the form Capsule containing oxycodone hydrochloride 20 mg

(a) *omit:*

				a	Oxycodone BNM	BZ	MP NP	C10764 C10771 C10772		20	0	20

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

[35] Schedule 1, Part 1, entry for Ozanimod

substitute:

Ozanimod	Capsule 920 micrograms	Oral		Zeposia	CJ	MP	C10162 C10172 C13946 C13993 C13995 C14002 C14003 C14004 C14005	P13995 P14003 P14004 P14005	28	3	28
						MP	C10162 C10172 C13946 C13993 C13995 C14002 C14003 C14004 C14005	P10162 P10172 P13946 P13993 P14002	28	5	28
	Pack containing 4 capsules 230 micrograms and 3 capsules 460 micrograms	Oral		Zeposia	CJ	MP	C10162 C10172 C14017		1	0	1

[36] Schedule 1, Part 1, entry for Pembrolizumab

insert in numerical order in the column headed "Circumstances": **C13948 C13949 C13986**

[37] Schedule 1, Part 1, entry for Pramipexole in the form Tablet containing pramipexole dihydrochloride monohydrate 125 micrograms

substitute:

Pramipexole	Tablet containing pramipexole dihydrochloride monohydrate 125 micrograms	Oral	a	APO-Pramipexole	TX	MP NP	C5363		30	0	30
			a	Sifrol	BY	MP NP	C5363 C5411	P5363	30	0	30
			a	Simipex 0.125	RW	MP NP	C5363 C5411	P5363	30	0	30
			a	Simpral	AF	MP NP	C5363		30	0	30
			a	Sifrol	BY	MP NP	C5363 C5411	P5411	30	2	30
			a	Simipex 0.125	RW	MP NP	C5363 C5411	P5411	30	2	30

[38] Schedule 1, Part 1, entry for Pramipexole in the form Tablet containing pramipexole dihydrochloride monohydrate 250 micrograms

substitute:

	Tablet containing pramipexole dihydrochloride monohydrate 250 micrograms	Oral	a	Sifrol	BY	MP NP	C5363 C5411	P5411	100	2	100
			a	Simipex 0.25	RW	MP NP	C5363 C5411	P5411	100	2	100
			a	APO-Pramipexole	TX	MP NP	C5363		100	5	100
			a	Sifrol	BY	MP NP	C5363 C5411	P5363	100	5	100
			a	Simipex 0.25	RW	MP NP	C5363 C5411	P5363	100	5	100
			a	Simpral	AF	MP NP	C5363		100	5	100

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

substitute:

Rivastigmine	Capsule 1.5 mg (as hydrogen tartrate)	Oral	Exelon	NV	MP	C13938 C13940 C13941		56	5	56
					NP	C13938		56	5	56
	Capsule 3 mg (as hydrogen tartrate)	Oral	Exelon	NV	MP	C13938 C13940 C13941		56	5	56
					NP	C13938		56	5	56
	Capsule 4.5 mg (as hydrogen tartrate)	Oral	Exelon	NV	MP	C13938 C13940 C13941		56	5	56
					NP	C13938		56	5	56
	Capsule 6 mg (as hydrogen tartrate)	Oral	Exelon	NV	MP	C13938 C13940 C13941		56	5	56
					NP	C13938		56	5	56
	Transdermal patch 9 mg	Transdermal	Exelon Patch 5	NV	MP	C13938 C13940 C13941		30	5	30

					NP	C13938		30	5	30
	Transdermal patch 18 mg	Transdermal	Exelon Patch 10	NV	MP	C13938 C13940 C13941		30	5	30
					NP	C13938		30	5	30
	Transdermal patch 27 mg	Transdermal	Exelon Patch 15	NV	MP	C13938 C13940 C13941		30	5	30
					NP	C13938		30	5	30

[40] Schedule 1, Part 1, entry for Sacituzumab govitecan

omit from the column headed "Circumstances": **C12670**

Schedule 1, Part 1, entry for Trimethoprim in the form Tablet 300 mg *[Maximum Quantity: 7; Number of Repeats: 1]*

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

			a	Trimethoprim Viatris	MQ	MP NP		7	1	7

[41] Schedule 1, Part 1, entry for Trimethoprim in the form Tablet 300 mg *[Maximum Quantity: 14; Number of Repeats: 2]*

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

			a	Trimethoprim Viatris	MQ	MP	P4243	14 CN4243	2 CN4243	7

[42] Schedule 1, Part 1, entry for Trimethoprim in the form Tablet 300 mg *[Maximum Quantity: 28; Number of Repeats: 0]*

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

			a	Trimethoprim Viatris	MQ	MP	P6163	28	0	7

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

substitute:

Upadacitinib	Tablet 15 mg	Oral	Rinvoq	VE	MP	C8638 C9064 C9431 C10340 C10356 C10376 C11488 C11813 C11886 C11944	P13959	28	1	28

	C11945 C11956 C11978 C12090 C12091 C12142 C12184 C12246 C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011				
MP	C8638 C9064 C9431 C10340 C10356 C10376 C11488 C11813 C11886 C11944 C11945 C11956 C11978 C12090 C12091 C12142 C12184 C12246 C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011	P8638 P9064 P10340 P10376 P11813 P11944 P11945 P11956 P12090 P12091 P12184 P12246 P12504	28	3	28
MP	C8638 C9064 C9431 C10340 C10356 C10376 C11488 C11813 C11886 C11944 C11945 C11956 C11978 C12090 C12091 C12142 C12184 C12246 C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011	P12499 P12508	28	4	28
MP	C8638 C9064 C9431 C10340 C10356 C10376 C11488 C11813	P9431 P10356 P11488 P11886 P11978 P12142 P12493 P12494	28	5	28

						C11886 C11944 C11945 C11956 C11978 C12090 C12091 C12142 C12184 C12246 C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011	P13930 P13958 P14011			
	Tablet 30 mg	Oral	Rinvoq	VE	MP	C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011	P13959	28	1	28
					MP	C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011	P12504	28	3	28
					MP	C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011	P12499 P12508	28	4	28
					MP	C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011	P12493 P12494 P13930 P13958 P14011	28	5	28
	Tablet 45 mg	Oral	Rinvoq	VE	MP	C11976 C13990 C13999 C14014		28	3	28

[44] Schedule 1, Part 1, after entry for Ustekinumab in the form Injection 45 mg in 0.5 mL *[Maximum Quantity: 2; Number of Repeats: 0]*

insert:

	Injection 90 mg in 1 mL single use pre-filled syringe	Injection	Stelara	JC	MP	C13927 C13952 C13955 C13988	P13927 P13955 P13988	1	0	1

						C14009 C14018			
					MP	C13927 C13952 C13955 C13988 C14009 C14018	P13952 P14009 P14018	1	1	1

[45] Schedule 1, Part 1, after entry for Vorinostat

insert:

Vosoritide	Powder for injection 400 micrograms with diluent	Injection	Voxzogo	IO	MP	C13929 C13977 C13998		30	5	10
	Powder for injection 560 micrograms with diluent	Injection	Voxzogo	IO	MP	C13929 C13977 C13998		30	5	10
	Powder for injection 1.2 mg with diluent	Injection	Voxzogo	IO	MP	C13929 C13977 C13998		30	5	10

[46] Schedule 1, Part 2, entry for Ampicillin

omit:

	Powder for injection 500 mg (as sodium)	Injection	Austrapen	AL	PDP			5	0	5
					MP NP			5	1	5

[47] Schedule 1, Part 2, after entry for Baricitinib in the form Tablet 4 mg

insert:

Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses, 2	Inhalation by a mouth	Symbicort Turbuhaler 400/12	AP	MP NP	C7979 C10121		1	5	1

[48] Schedule 1, Part 2, after entry for Dipyridamole with aspirin

insert:

Donepezil	Tablet containing donepezil hydrochloride 5 mg	Oral	a	APO-Donepezil	TX	MP	C10099 C10100	28	5	28
			a	Arazil	AF	MP	C10099 C10100	28	5	28
			a	Aricept	PF	MP	C10099 C10100	28	5	28
			a	Aridon 5	RW	MP	C10099 C10100	28	5	28
			a	Aridon APN 5	RF	MP	C10099 C10100	28	5	28
			a	Donepezil GH	HQ	MP	C10099 C10100	28	5	28
			a	Donepezil Sandoz	SZ	MP	C10099 C10100	28	5	28
			a	Donepezil-DRLA	RZ	MP	C10099 C10100	28	5	28
			a	NOUMED DONEPEZIL	VO	MP	C10099 C10100	28	5	28
	Tablet containing donepezil hydrochloride 10 mg	Oral	a	APO-Donepezil	TX	MP	C10099 C10100	28	5	28
			a	Arazil	AF	MP	C10099 C10100	28	5	28
			a	Aricept	PF	MP	C10099 C10100	28	5	28
			a	Aridon 10	RW	MP	C10099 C10100	28	5	28
			a	Aridon APN 10	RF	MP	C10099 C10100	28	5	28
			a	Donepezil GH	HQ	MP	C10099 C10100	28	5	28
			a	Donepezil Sandoz	SZ	MP	C10099 C10100	28	5	28
			a	Donepezil-DRLA	RZ	MP	C10099 C10100	28	5	28
			a	NOUMED DONEPEZIL	VO	MP	C10099 C10100	28	5	28

[49] Schedule 1, Part 2, after entry for Etanercept in the form Injections 50 mg in 1 mL single use pre-filled syringes, 4

insert:

Galantamine	Capsule (prolonged release) 8 mg (as hydrobromide)	Oral	a	APO-Galantamine MR	TX	MP	C10099 C10100	28	5	28
			a	Galantyl	AF	MP	C10099 C10100	28	5	28
			a	Gamine XR	RW	MP	C10099 C10100	28	5	28
			a	Reminyl	JC	MP	C10099 C10100	28	5	28
	Capsule (prolonged release) 16 mg (as hydrobromide)	Oral	a	APO-Galantamine MR	TX	MP	C10099 C10100	28	5	28
			a	Galantyl	AF	MP	C10099 C10100	28	5	28
			a	Gamine XR	RW	MP	C10099 C10100	28	5	28
			a	Reminyl	JC	MP	C10099 C10100	28	5	28
	Capsule (prolonged release) 24 mg (as hydrobromide)	Oral	a	APO-Galantamine MR	TX	MP	C10099 C10100	28	5	28
			a	Galantyl	AF	MP	C10099 C10100	28	5	28
			a	Gamine XR	RW	MP	C10099 C10100	28	5	28
			a	Reminyl	JC	MP	C10099 C10100	28	5	28

[50] Schedule 1, Part 2, omit entry for Hydromorphone

[51] Schedule 1, Part 2, after entry for Losartan in the form Tablet containing losartan potassium 50 mg

insert:

Memantine	Tablet containing memantine hydrochloride 10 mg	Oral	a	APO-Memantine	TX	MP	C10098 C10184	56	5	56
			a	Ebixa	LU	MP	C10098 C10184	56	5	56
			a	Memantine generichealth	GQ	MP	C10098 C10184	56	5	56
			a	Memanxa	RW	MP	C10098 C10184	56	5	56
	Tablet containing memantine	Oral	a	APO-Memantine	TX	MP	C10098 C10184	28	5	28

	hydrochloride 20 mg								
		a	Ebixa	LU	MP	C10098 C10184	28	5	28
		a	Memantine generichealth	GQ	MP	C10098 C10184	28	5	28

[52] Schedule 1, Part 2, after entry for Risedronic acid and calcium

insert:

Rivastigmine	Capsule 1.5 mg (as hydrogen tartrate)	Oral	Exelon	NV	MP	C10099 C10100	56	5	56
	Capsule 3 mg (as hydrogen tartrate)	Oral	Exelon	NV	MP	C10099 C10100	56	5	56
	Capsule 4.5 mg (as hydrogen tartrate)	Oral	Exelon	NV	MP	C10099 C10100	56	5	56
	Capsule 6 mg (as hydrogen tartrate)	Oral	Exelon	NV	MP	C10099 C10100	56	5	56
	Transdermal patch 9 mg	Transdermal	Exelon Patch 5	NV	MP	C10099 C10100	30	5	30
	Transdermal patch 18 mg	Transdermal	Exelon Patch 10	NV	MP	C10099 C10100	30	5	30
	Transdermal patch 27 mg	Transdermal	Exelon Patch 15	NV	MP	C10099 C10100	30	5	30

[53] Schedule 1, Part 2, omit entry for Triglycerides, medium chain

[54] Schedule 4, Part 1, entry for Abiraterone

substitute:

Abiraterone	C13945			Castration resistant metastatic carcinoma of the prostate The treatment must be used in combination with a corticosteroid; AND The treatment must not be used in combination with chemotherapy; AND Patient must have a WHO performance status of 2 or less; AND The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits; 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	Compliance with Authority Required procedures

				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.	

[55] Schedule 4, Part 1, after entry for Abiraterone

insert:

Abiraterone and methylprednisolone	C13992			Castration resistant metastatic carcinoma of the prostate The treatment must not be used in combination with chemotherapy; AND Patient must have a WHO performance status of 2 or less; AND The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits; 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.	Compliance with Authority Required procedures

[56] Schedule 4, Part 1, after entry for Artemether with lumefantrine

insert:

Asciminib	C13923	P13923		Chronic Myeloid Leukaemia (CML) Continuing treatment for patients without T315I mutation The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have received initial PBS-subsidised treatment with this drug for this condition; AND Patient must be undergoing first continuing treatment with this drug, demonstrating either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%; OR Patient must be undergoing subsequent continuing treatment with this drug, demonstrating a 12-month response of either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%. A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 13923
	C13925	P13925		Chronic Myeloid Leukaemia (CML) Initial PBS-subsidised treatment for patients with T315I mutation The condition must not be in the blast phase; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must be expressing the T315I mutation confirmed through a bone marrow biopsy pathology report; AND The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND Patient must have failed an adequate trial of at least one tyrosine kinase inhibitor as confirmed through a pathology report from an Approved Pathology Authority; OR Patient must have experienced intolerance, not failure to respond, to at least one tyrosine kinase inhibitor as confirmed	Compliance with Written Authority Required procedures

				through a pathology report from an Approved Pathology Authority. Failure of an adequate trial of a tyrosine kinase inhibitor is defined as: 1. Lack of response defined as either: (i) failure to achieve a haematological response after a minimum of 3 months therapy; or (ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive (Ph+) cells; or (iii) failure to achieve or maintain a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy; OR 2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph+ cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR 3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR 4. Development of accelerated phase in a patient previously prescribed a TKI inhibitor for any phase of chronic myeloid leukaemia; OR 5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during TKI therapy in patients with accelerated phase chronic myeloid leukaemia. Accelerated phase is defined by the presence of 1 or more of the following: 1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or 2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or 3. Peripheral basophils greater than or equal to 20%; or 4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or 5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome). The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or (ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and (iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation; and (iv) where there has been a loss of response to imatinib or dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement. 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). Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib, ponatinib or asciminib at any	

				one time and must not be receiving concomitant interferon alfa therapy Up to a maximum of 18 months of treatment may be authorised under this initial restriction.	
	C13950	P13950		Chronic Myeloid Leukaemia (CML) Initial PBS-subsidised treatment for patients without T315I mutation The treatment must be the sole PBS-subsidised therapy for this condition; AND The condition must not be in the blast phase; AND The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND Patient must have failed an adequate trial of at least two tyrosine kinase inhibitors; OR Patient must have experienced intolerance, not failure to respond, to at least two tyrosine kinase inhibitors; OR Patient must have failed an adequate trial of at least one tyrosine kinase inhibitor with intolerance to at least another tyrosine kinase inhibitor. Failure of an adequate trial of a tyrosine kinase inhibitor is defined as: 1. Lack of response defined as either: (i) failure to achieve a haematological response after a minimum of 3 months therapy; or (ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive (Ph+) cells; or (iii) failure to achieve or maintain a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy; OR 2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph+ cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR 3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR 4. Development of accelerated phase in a patient previously prescribed a TKI inhibitor for any phase of chronic myeloid leukaemia; OR 5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during TKI therapy in patients with accelerated phase chronic myeloid leukaemia. Accelerated phase is defined by the presence of 1 or more of the following: 1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or 2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or 3. Peripheral basophils greater than or equal to 20%; or 4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or 5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).	Compliance with Authority Required procedures
	C14008	P14008		Chronic Myeloid Leukaemia (CML) Continuing Treatment for patients with T315I mutation	Compliance with Authority Required

				Patient must have received initial PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must be undergoing first continuing treatment with this drug, demonstrating either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%; OR Patient must be undergoing subsequent continuing treatment with this drug, demonstrating a 12-month response of either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%. A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records. The continuing application for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (i) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a major cytogenetic response [see Note explaining definitions of response]; or (ii) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. 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). Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib, ponatinib or asciminib at any one time and must not be receiving concomitant interferon alfa therapy	procedures

[57] Schedule 4, Part 1, entry for Budesonide

(a) *omit:*

	C12837	P12837		Eosinophilic oesophagitis Subsequent continuing treatment - Maintenance of remission Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; OR Patient must have previously received PBS-subsidised treatment with this drug for this condition under the - Transitioning from non-PBS to PBS-subsided treatment - Grandfather treatment restriction; AND The condition must not have progressed while being treated with this drug. Must be treated by a gastroenterologist or in consultation with a gastroenterologist.	Compliance with Authority Required procedures
	C12909	P12909		Eosinophilic oesophagitis Transitioning from non-PBS to PBS-subsidised treatment - Grandfather treatment Patient must have previously received non-PBS-subsidised treatment with a corticosteroid for this condition prior to 1 May 2022; AND Patient must be receiving non-PBS treatment with a corticosteroid for this condition at the time of application; AND Patient must have had, prior to commencement of non-PBS-subsidised treatment with a corticosteroid, a history of symptoms of oesophageal dysfunction; AND Patient must have had, prior to commencement of non-PBS-subsidised treatment with a corticosteroid, eosinophilic infiltration	Compliance with Authority Required procedures

				of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy confirming the presence of at least 15 eosinophils in at least one high power field (hpf); corresponding to approximately 60 eosinophils per mm^2hpf; AND Patient must have documented evidence that they are currently in histologic remission, where remission is defined as a peak eosinophil count of less than 5 eosinophils per high power field (hpf); corresponding to less than 16 eosinophils per mm^2hpf on oesophageal biopsy. Must be treated by a gastroenterologist. A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the subsequent continuing treatment criteria. Symptoms of oesophageal dysfunction include at least one of the following: dysphasia, odynophagia, transient or self-cleared food impaction, chest pain, epigastric discomfort, vomiting/regurgitation. Histologic assessment should be based on the peak eosinophils count derived from the evaluation of at least eight oesophageal biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction). The histologic assessment should, where possible, be performed by the same physician who confirmed the diagnosis of eosinophilic oesophagitis in the patient. This assessment, which will be used to determine eligibility for continuing treatment, should have been conducted after the patient has completed 8 weeks of the initial treatment course and no later than 2 weeks prior to the patient completing the initial treatment course, to avoid an interruption to supply. Where a histologic assessment is not undertaken and the results submitted, the patient will not be eligible for ongoing treatment.	

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

	C13968	P13968		Eosinophilic oesophagitis Subsequent continuing treatment - Maintenance of remission Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND The condition must not have progressed while being treated with this drug. Must be treated by a gastroenterologist or in consultation with a gastroenterologist.	Compliance with Authority Required procedures

[58] Schedule 4, Part 1, entry for Daratumumab

(a) *omit:*

	C13744	P13744		Newly diagnosed systemic light chain amyloidosis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must be continuing treatment with this drug that was commenced as non-PBS-subsidised supply prior to 1 January 2023; AND The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis; AND The condition must have been, prior to the first dose of the non-PBS-subsidised supply, untreated with drug therapy, including this drug, irrespective of whether the diagnosis had been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis); 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. Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist); AND	Compliance with Written Authority Required procedures

				Patient must be undergoing concomitant treatment limited to each of: (i) bortezomib, (ii) cyclophosphamide, (iii) dexamethasone, at certain weeks of treatment as outlined in the drug's approved Product Information; AND Patient must be undergoing continuing treatment that does not extend treatment duration beyond whichever comes first: (i) disease progression, (ii) 96 cumulative weeks from the first administered dose, once in a lifetime. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include: Details of the histological evidence supporting the diagnosis of systemic light chain amyloidosis, limited to: (i) the date of the histology result, which was within 4 weeks prior to the commencement of non-PBS-subsidised therapy, (ii) the name of pathologist/pathology provider, (iii) the site of biopsy. 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). Determine an appropriate number of repeat prescriptions for this authority application in line with either: (i) Where the patient has received less than 10 non-PBS-subsidised doses, prescribe a number of repeat prescriptions up to the balance of: 15 doses less the number of non-PBS-subsidised doses; or (ii) Where the patient has received at least 10 non-PBS-subsidised doses, prescribe no more than 5 repeat prescriptions.	
	C13751	P13751		Newly diagnosed systemic light chain amyloidosis Initial treatment from week 0 to week 24 The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis; AND The condition must be untreated with drug therapy, including this drug, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis); AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation. Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist); AND Patient must be undergoing concomitant treatment limited to each of: (i) bortezomib, (ii) cyclophosphamide, (iii) dexamethasone, at certain weeks of treatment as outlined in the drug's approved Product Information. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include: Details of the histological evidence supporting the diagnosis of systemic light chain amyloidosis, limited to: (i) the date of the histology result, which is no older than 4 weeks at the time of making this authority application, (ii) the name of pathologist/pathology provider, (iii) the site of biopsy. 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:*

	C13944	P13944		Newly diagnosed systemic light chain amyloidosis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must be continuing treatment with this drug that was commenced as non-PBS-subsidised supply prior to 1 January	Compliance with Written Authority Required procedures

				2023; AND The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis; AND The condition must have been, prior to the first dose of the non-PBS-subsidised supply, untreated with drug therapy, including this drug, irrespective of whether the diagnosis had been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis); 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. Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist); AND Patient must be undergoing concomitant treatment limited to each of: (i) bortezomib, (ii) cyclophosphamide, (iii) dexamethasone, at certain weeks of treatment as outlined in the drug's approved Product Information; AND Patient must be undergoing continuing treatment that does not extend treatment duration beyond whichever comes first: (i) disease progression, (ii) 96 cumulative weeks from the first administered dose, once in a lifetime. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include: Details of the histological evidence supporting the diagnosis of systemic light chain amyloidosis, limited to: (i) the name of pathologist/pathology provider, (ii) the site of biopsy 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). Determine an appropriate number of repeat prescriptions for this authority application in line with either: (i) Where the patient has received less than 10 non-PBS-subsidised doses, prescribe a number of repeat prescriptions up to the balance of: 15 doses less the number of non-PBS-subsidised doses; or (ii) Where the patient has received at least 10 non-PBS-subsidised doses, prescribe no more than 5 repeat prescriptions.	
	C14015	P14015		Newly diagnosed systemic light chain amyloidosis Initial treatment from week 0 to week 24 The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis; AND The condition must be untreated with drug therapy, including this drug, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis); AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation. Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist); AND Patient must be undergoing concomitant treatment limited to each of: (i) bortezomib, (ii) cyclophosphamide, (iii) dexamethasone, at certain weeks of treatment as outlined in the drug's approved Product Information. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include: Details of the histological evidence supporting the diagnosis of systemic light chain amyloidosis, limited to: (i) the name of pathologist/pathology provider, (ii) the site of biopsy 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	Compliance with Written Authority Required procedures

				website specified in the Administrative Advice).	

[59] Schedule 4, Part 1, entry for Donepezil

(a) *omit from the column headed "Purposes Code" for the circumstance code "C10099":* **P10099**

(b) *omit from the column headed "Purposes Code" for the circumstance code "C10100":* **P10100**

(c) *omit:*

	C10107	P10107		Mild to moderately severe Alzheimer disease Initial 1 Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified. Up to a maximum of 2 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. This application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment with this drug with this strength.	Compliance with Authority Required procedures
	C10108	P10108		Mild to moderately severe Alzheimer disease Continuing Patient must have received six months of sole PBS-subsidised initial therapy with this drug and has received a written authority approval; AND Patient must demonstrate a clinically meaningful response to the initial treatment; AND The treatment must be the sole PBS-subsidised therapy for this condition. Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit. Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use. Re-assessments for a clinically meaningful response are to be undertaken and documented every six months. Clinically meaningful response to treatment is demonstrated in the following areas: Patient's quality of life including but not limited to level of independence and happiness; Patient's cognitive function including but not limited to memory, recognition and interest in environment; Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.	Compliance with Authority Required procedures - Streamlined Authority Code 10108
	C10110	P10110		Mild to moderately severe Alzheimer disease Initial 1 Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures

				A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs. Patients who qualify under this criterion are from 1 or more of the following groups: (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background; (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate; (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test; (4) Intellectual (developmental or acquired) disability, eg Down's syndrome; (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test; (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment. Up to a maximum of 2 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. This application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment with this drug with this strength.	

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

	C13938			Mild to moderately severe Alzheimer disease Continuing Patient must have received six months of sole PBS-subsidised initial therapy with this drug; AND Patient must demonstrate a clinically meaningful response to the initial treatment; AND The treatment must be the sole PBS-subsidised therapy for this condition. Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit. Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use. Re-assessments for a clinically meaningful response are to be undertaken and documented every six months. Clinically meaningful response to treatment is demonstrated in the following areas: Patient's quality of life including but not limited to level of independence and happiness; Patient's cognitive function including but not limited to memory, recognition and interest in environment; Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.	Compliance with Authority Required procedures - Streamlined Authority Code 13938
	C13940			Mild to moderately severe Alzheimer disease Initial Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.	Compliance with Authority Required procedures

				Patients who qualify under this criterion are from 1 or more of the following groups: (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background; (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate; (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test; (4) Intellectual (developmental or acquired) disability, eg Down's syndrome; (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test; (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment. Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.	
	C13941			Mild to moderately severe Alzheimer disease Initial Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified. Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.	Compliance with Authority Required procedures

[60] Schedule 4, Part 1, entry for Galantamine

(a) *omit from the column headed "Purposes Code" for the circumstance code "C10099":* **P10099**

(b) *omit from the column headed "Purposes Code" for the circumstance code "C10100":* **P10100**

(c) *omit:*

	C10107	P10107		Mild to moderately severe Alzheimer disease Initial 1 Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified. Up to a maximum of 2 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. This application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment with this drug with this strength.	Compliance with Authority Required procedures
	C10108	P10108		Mild to moderately severe Alzheimer disease Continuing Patient must have received six months of sole PBS-subsidised initial therapy with this drug and has received a written authority approval; AND Patient must demonstrate a clinically meaningful response to the initial treatment; AND	Compliance with Authority Required procedures - Streamlined Authority

				The treatment must be the sole PBS-subsidised therapy for this condition. Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit. Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use. Re-assessments for a clinically meaningful response are to be undertaken and documented every six months. Clinically meaningful response to treatment is demonstrated in the following areas: Patient's quality of life including but not limited to level of independence and happiness; Patient's cognitive function including but not limited to memory, recognition and interest in environment; Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.	Code 10108
	C10110	P10110		Mild to moderately severe Alzheimer disease Initial 1 Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs. Patients who qualify under this criterion are from 1 or more of the following groups: (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background; (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate; (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test; (4) Intellectual (developmental or acquired) disability, eg Down's syndrome; (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test; (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment. Up to a maximum of 2 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. This application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment with this drug with this strength.	Compliance with Authority Required procedures

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

	C13938			Mild to moderately severe Alzheimer disease Continuing Patient must have received six months of sole PBS-subsidised initial therapy with this drug; AND Patient must demonstrate a clinically meaningful response to the initial treatment; AND The treatment must be the sole PBS-subsidised therapy for this condition. Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.	Compliance with Authority Required procedures - Streamlined Authority Code 13938

				Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use. Re-assessments for a clinically meaningful response are to be undertaken and documented every six months. Clinically meaningful response to treatment is demonstrated in the following areas: Patient's quality of life including but not limited to level of independence and happiness; Patient's cognitive function including but not limited to memory, recognition and interest in environment; Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.	
	C13940			Mild to moderately severe Alzheimer disease Initial Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs. Patients who qualify under this criterion are from 1 or more of the following groups: (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background; (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate; (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test; (4) Intellectual (developmental or acquired) disability, eg Down's syndrome; (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test; (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment. Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.	Compliance with Authority Required procedures
	C13941			Mild to moderately severe Alzheimer disease Initial Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified. Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.	Compliance with Authority Required procedures

[61] Schedule 4, Part 1, entry for Hydromorphone

(a) *omit:*

	C10752	P10752		Chronic severe pain Continuing PBS treatment after 1 June 2020	Compliance with Authority Required

				Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment: (i) is less than 12 months; or (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months. Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).	procedures - Streamlined Authority Code 10752
	C10753	P10753		Chronic severe pain Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months The condition must require daily, continuous, long term opioid treatment; AND Patient must not be opioid naive; AND Patient must have cancer pain; OR 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. Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment: (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or (iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months. Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).	Compliance with Authority Required procedures - Streamlined Authority Code 10753
	C10754	P10754		Chronic severe pain	Compliance with

				Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months The condition must require daily, continuous, long term opioid treatment; AND Patient must not be opioid naive; AND Patient must have cancer pain; OR 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. Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).	Authority Required procedures - Streamlined Authority Code 10754

(b) *omit:*

	C11696	P11696		Severe disabling pain Patient must not be opioid naive; 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. Patient must be undergoing palliative care. Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).	Compliance with Authority Required procedures

[62] Schedule 4, Part 1, entry for Ipilimumab

omit:

	C11394			Stage IV (metastatic) non-small cell lung cancer (NSCLC) Grandfather treatment (treatment of a patient commenced on non-PBS-subsidised combination treatment as first-line drug therapy) Patient must have previously received non-PBS-subsidised treatment with this drug for this indication prior to 1 April 2021; AND The condition must be squamous type non-small cell lung cancer (NSCLC); AND Patient must not have been treated for this condition in the metastatic setting prior to initiating non-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 Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS-subsidised treatment with this drug for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority Code 11394

				The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first; AND The treatment must be in combination with platinum-based chemotherapy for the first two cycles; AND The treatment must be in combination with nivolumab.	

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

insert in numerical order after existing text:

	C13921	P13921		Stage IV clear cell variant renal cell carcinoma (RCC) Initial treatment Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug and pembrolizumab of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records; AND The condition must be untreated; AND Patient must have a WHO performance status of 2 or less. Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 13921
	C13972	P13972		Stage IV clear cell variant renal cell carcinoma (RCC) 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. Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; OR Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose. In a patient who has experienced an intolerance to pembrolizumab, details of intolerance must be documented in the patient's medical record.	Compliance with Authority Required procedures - Streamlined Authority Code 13972
	C14007	P14007		Stage IV clear cell variant renal cell carcinoma (RCC) Transitioning from non-PBS to PBS-subsided supply - Grandfather arrangements Patient must be currently receiving non-PBS-subsidised treatment with this drug for this condition, with treatment having commenced prior to 1 May 2023; AND Patient must have had a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug and pembrolizumab of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records if not already documented; AND	Compliance with Authority Required procedures - Streamlined Authority Code 14007

				The treatment must be occurring in a patient where each of the following is true: (i) the patient's WHO performance status was no higher than 2 at treatment initiation, (ii) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (c) as monotherapy after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose, (iii) the condition was untreated at the time of treatment initiation, (iv) disease progression has not occurred whilst on treatment.	

[64] Schedule 4, Part 1, entry for Memantine

(a) *omit from the column headed "Purposes Code" for the circumstance code "C10098":* **P10098**

(b) *omit:*

	C10103	P10103		Moderately severe Alzheimer disease Initial 1 Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14. Up to a maximum of 2 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. This application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment with this drug with this strength.	Compliance with Authority Required procedures
	C10104	P10104		Moderately severe Alzheimer disease Continuing Patient must have received six months of sole PBS-subsidised initial therapy with this drug and has received a written authority approval; AND Patient must demonstrate a clinically meaningful response to the initial treatment; AND The treatment must be the sole PBS-subsidised therapy for this condition. Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit. Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use. Re-assessments for a clinically meaningful response are to be undertaken and documented every six months. Clinically meaningful response to treatment is demonstrated in the following areas: Patient's quality of life including but not limited to level of independence and happiness; Patient's cognitive function including but not limited to memory, recognition and interest in environment; Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.	Compliance with Authority Required procedures - Streamlined Authority Code 10104
	C10183	P10183		Moderately severe Alzheimer disease Initial 1 Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination	Compliance with Authority Required procedures

				(SMMSE) score of 9 or less; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs. Patients who qualify under this criterion are from 1 or more of the following groups: (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background; (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate; (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test; (4) Intellectual (developmental or acquired) disability, eg Down's syndrome; (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test; (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment. Up to a maximum of 2 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. This application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment with this drug with this strength.	

(c) *omit from the column headed "Purposes Code" for the circumstance code "C10184":* **P10184**

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

	C13936			Moderately severe Alzheimer disease Initial Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs. Patients who qualify under this criterion are from 1 or more of the following groups: (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background; (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate; (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test; (4) Intellectual (developmental or acquired) disability, eg Down's syndrome; (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test; (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment. Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.	Compliance with Authority Required procedures
	C13966			Moderately severe Alzheimer disease	Compliance with

				Continuing Patient must have received six months of sole PBS-subsidised initial therapy with this drug; AND Patient must demonstrate a clinically meaningful response to the initial treatment; AND The treatment must be the sole PBS-subsidised therapy for this condition. Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit. Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use. Re-assessments for a clinically meaningful response are to be undertaken and documented every six months. Clinically meaningful response to treatment is demonstrated in the following areas: Patient's quality of life including but not limited to level of independence and happiness; Patient's cognitive function including but not limited to memory, recognition and interest in environment; Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.	Authority Required procedures - Streamlined Authority Code 13966
	C14000			Moderately severe Alzheimer disease Initial Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14. Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.	Compliance with Authority Required procedures

[65] Schedule 4, Part 1, entry for Methylphenidate

substitute:

Methylphenidate	C6226			Attention deficit hyperactivity disorder Treatment must be in accordance with the law of the relevant State or Territory.	Compliance with Authority Required procedures
	C10717			Attention deficit hyperactivity disorder Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive. Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events; AND Patient must require continuous coverage over 12 hours; AND The treatment must not exceed a maximum daily dose of 72 mg with this drug.	Compliance with Authority Required procedures
	C13922			Attention deficit hyperactivity disorder Patient must be aged between the ages of 6 and 18 years inclusive; OR Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of	Compliance with Authority Required procedures

				age; OR Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age. Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events; AND Patient must require continuous coverage over 8 hours; AND The treatment must not exceed a maximum daily dose of 80 mg with this drug. A retrospective diagnosis of ADHD for the purposes of administering this restriction is: (i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and (ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party, has occurred and which supports point (i) above.	

[66] Schedule 4, Part 1, entry for Naltrexone

substitute:

Naltrexone	C13967			Alcohol dependence The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence/controlled consumption.	Compliance with Authority Required procedures - Streamlined Authority Code 13967

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

omit:

	C13420			Progressive fibrosing Interstitial lung disease Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this indication of 'progressive fibrosing interstitial lung disease' (not 'idiopathic pulmonary fibrosis') prior to 1 May 2022; AND The condition must be diagnosed through a multidisciplinary team; AND The condition must have chest imaging through high resolution computed tomography (HRCT) that was no older than 12 months at the time non-PBS supply was initiated, to support the diagnosis of the PBS indication; AND The condition must have displayed, through HRCT, an affected area of no less than 10% (after rounding to the nearest multiple of 5) at the time non-PBS supply was initiated; AND Patient must have had a forced vital capacity (FVC) measurement no less than 45% predicted, prior to initiating non-PBS supply treatment with this drug for this indication, that was no older than 2 years at the time of non-PBS subsidised treatment initiation, in addition to being adjusted for each of: (i) age, (ii) gender, (iii) height; AND The condition must have been of a progressive nature prior to initiating non-PBS-subsidised treatment, observed by, in any time period leading up to the initiation of non-PBS-subsidised supply, any of: (i) a worsening in relative FVC% predicted measurement of no less than 10%, (ii) a worsening in relative FVC% predicted measurement in the range 5-10%, combined with worsening of respiratory symptoms, (iii) a worsening in relative FVC% predicted measurement in the range 5-10%, combined with increases in fibrosis observed on HRCT; document at least one of (i) to (iii) in the patient's medical records;	Compliance with Written Authority Required procedures

				AND Patient must have had a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7 at the time of initiating non-PBS-subsidised supply; AND Patient must not have had an acute respiratory infection at the time of FVC measurement; AND Patient must have had, prior to initiating non-PBS-subsidised supply, a diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin that was both: (i) at least 30% predicted, (ii) no greater than 80% predicted; AND The condition must not be interstitial lung disease due to idiopathic pulmonary fibrosis (apply under the correct PBS listing if it is); AND The condition must not be due to reversible causes (e.g. drug toxicity). Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician; AND Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following: (i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement. Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; 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) A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis. Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records.	

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

(a) *omit:*

	C8573			Stage IV clear cell variant renal cell carcinoma (RCC) Induction treatment The condition must not have previously been treated; AND The condition must be classified as intermediate to poor risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC); AND Patient must have a WHO performance status of 2 or less; AND The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition. Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 8573

(b) *omit:*

	C11469			Stage IV (metastatic) non-small cell lung cancer (NSCLC) Grandfather treatment (treatment of a patient commenced on non-PBS-subsidised combination treatment as first-line drug therapy) Patient must have previously received non-PBS-subsidised treatment with this drug for this indication prior to 1 April 2021; AND The condition must be squamous type non-small cell lung cancer (NSCLC); AND Patient must not have been treated for this condition in the metastatic setting prior to initiating non-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 Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS-subsidised treatment with this drug for this condition; AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND Patient must not have received treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer prior to initiating treatment with this drug for this PBS indication; AND The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first; AND The treatment must be in combination with platinum-based chemotherapy for the first two cycles; AND The treatment must be in combination with ipilimumab.	Compliance with Authority Required procedures - Streamlined Authority Code 11469

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

	C14001			Stage IV clear cell variant renal cell carcinoma (RCC) Induction treatment The condition must not have previously been treated; AND Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records; AND Patient must have a WHO performance status of 2 or less; AND The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition. Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 14001

[69] Schedule 4, Part 1, entry for Olaparib

omit:

	C12589	P12589		Castration resistant metastatic carcinoma of the prostate Transitioning from non-PBS to PBS-subsided treatment - Grandfather arrangements Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 April 2022; AND The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation; AND	Compliance with Authority Required procedures

				The treatment must not be subsidised in combination with: (i) chemotherapy, (ii) a novel hormonal drug; AND The condition must have progressed following prior treatment that included a novel hormonal drug for this condition (metastatic/non-metastatic disease), prior to initiating non-PBS-subsidised treatment with this drug; AND Patient must have had a WHO performance status of 2 or less prior to initiating non-PBS-subsidised treatment. Patient must be undergoing continuing treatment with this drug where non-PBS-subsidised treatment was for untreated (with this drug) disease which also has not progressed on non-PBS-subsidised treatment.	

[70] Schedule 4, Part 1, entry for Ozanimod

substitute:

Ozanimod	C10162	P10162		Multiple sclerosis Initial treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by 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 have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support). 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 10162
	C10172	P10172		Multiple sclerosis Continuing treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not show continuing progression of disability while on treatment with this drug; AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 10172
	C13946	P13946		Moderate to severe ulcerative colitis Continuing treatment - balance of supply Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received insufficient therapy with this drug for this condition 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.	Compliance with Authority Required procedures
	C13993	P13993		Moderate to severe ulcerative colitis Transitioning from non-PBS to PBS-subsided treatment - Grandfather arrangements Must be treated by a gastroenterologist (code 87); OR	Compliance with Written Authority Required procedures

				Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2023; AND Patient must be receiving treatment with this drug for this condition at the time of application; AND The condition must have responded inadequately to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for at least 3 consecutive months prior to treatment initiation with this drug; OR Patient must have experienced a severe intolerance to the above therapy leading to permanent treatment discontinuation; AND The condition must have responded inadequately to azathioprine at a dose of at least 2 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; OR The condition must have responded inadequately to 6-mercaptopurine at a dose of at least 1 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; OR The condition must have responded inadequately to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, followed by an inadequate response to at least 3 consecutive months of treatment with an appropriately dosed thiopurine agent, prior to treatment initiation with this drug; OR Patient must have experienced a severe intolerance to each of the above 3 therapies leading to permanent treatment discontinuation; AND Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing non-PBS-subsidised treatment with this drug for this condition; OR Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced non-PBS-subsidised treatment with this drug for this condition where a Mayo clinic or partial Mayo clinic baseline assessment is not available; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes: (i) the completed baseline Mayo clinic or partial Mayo clinic calculation sheet prior to initiating treatment (if available) including the date of assessment; (ii) the date of commencement of this drug. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. The assessment of the patient's response to this PBS-subsidised course of therapy must be conducted no later than 4 weeks from the cessation of the treatment course. 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. Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to	

				sustain a response. At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.	
	C13995	P13995		Moderate to severe ulcerative colitis Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND Patient must have a Mayo clinic score greater than or equal to 6; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score). Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application. An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.	Compliance with Written Authority Required procedures

				If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. A maximum of 16 weeks of treatment with this drug will be approved under this criterion.	
	C14002	P14002		Moderate to severe ulcerative colitis Continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug. Patient must be at least 18 years of age. Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient 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.	Compliance with Authority Required procedures
	C14003	P14003		Moderate to severe ulcerative colitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have 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. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and	Compliance with Written Authority Required procedures

				(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. A maximum of 16 weeks of treatment with this drug will be approved under this criterion.	
	C14004	P14004		Moderate to severe ulcerative colitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; 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 a Mayo clinic score greater than or equal to 6; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score). Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application. An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.	Compliance with Written Authority Required procedures

				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 maximum of 16 weeks of treatment with this drug will be approved under this criterion.	
	C14005	P14005		Moderate to severe ulcerative colitis Initial 1 (new patient) or 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 Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have 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.	Compliance with Authority Required procedures
	C14017			Moderate to severe ulcerative colitis Dose escalation occurring at initial treatment or re-initiation of treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].	Compliance with Authority Required procedures - Streamlined Authority Code 14017

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

insert in numerical order after existing text:

	C13948			Stage IV clear cell variant renal cell carcinoma (RCC) Initial treatment Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records; AND The condition must be untreated; AND Patient must have a WHO performance status of 2 or less. Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR	Compliance with Authority Required procedures - Streamlined Authority Code 13948

				Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	
	C13949			Stage IV clear cell variant renal cell carcinoma (RCC) 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. Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.	Compliance with Authority Required procedures - Streamlined Authority Code 13949
	C13986			Stage IV clear cell variant renal cell carcinoma (RCC) Transitioning from non-PBS to PBS-subsided supply - Grandfather arrangements Patient must be currently receiving non-PBS-subsidised treatment with this drug for this condition, with treatment having commenced prior to 1 May 2023; AND Patient must have had a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records if not already documented; AND The treatment must be occurring in a patient where each of the following is true: (i) the patient's WHO performance status was no higher than 2 at treatment initiation, (ii) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (iii) the condition was untreated at the time of treatment initiation, (iv) disease progression has not occurred whilst on treatment, (v) treatment is occurring with a dosing regimen specified in this drug's approved Australian Product Information, (vi) this prescription does not extend treatment beyond 24 months from the first administered dose. Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	Compliance with Authority Required procedures - Streamlined Authority Code 13986

[72] Schedule 4, Part 1, entry for Rivastigmine

(a) *omit from the column headed "Purposes Code" for the circumstance code "C10099":* **P10099**

(b) *omit from the column headed "Purposes Code" for the circumstance code "C10100":* **P10100**

(c) *omit:*

	C10107	P10107		Mild to moderately severe Alzheimer disease Initial 1 Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified. Up to a maximum of 2 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. This application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment with this drug with this strength.	Compliance with Authority Required procedures
	C10108	P10108		Mild to moderately severe Alzheimer disease Continuing Patient must have received six months of sole PBS-subsidised initial therapy with this drug and has received a written authority approval; AND Patient must demonstrate a clinically meaningful response to the initial treatment; AND The treatment must be the sole PBS-subsidised therapy for this condition. Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit. Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use. Re-assessments for a clinically meaningful response are to be undertaken and documented every six months. Clinically meaningful response to treatment is demonstrated in the following areas: Patient's quality of life including but not limited to level of independence and happiness; Patient's cognitive function including but not limited to memory, recognition and interest in environment; Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.	Compliance with Authority Required procedures - Streamlined Authority Code 10108
	C10110	P10110		Mild to moderately severe Alzheimer disease Initial 1 Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs. Patients who qualify under this criterion are from 1 or more of the following groups: (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background; (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate; (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;	Compliance with Authority Required procedures

				(4) Intellectual (developmental or acquired) disability, eg Down's syndrome; (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test; (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment. Up to a maximum of 2 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. This application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment with this drug with this strength.	

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

	C13938			Mild to moderately severe Alzheimer disease Continuing Patient must have received six months of sole PBS-subsidised initial therapy with this drug; AND Patient must demonstrate a clinically meaningful response to the initial treatment; AND The treatment must be the sole PBS-subsidised therapy for this condition. Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit. Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use. Re-assessments for a clinically meaningful response are to be undertaken and documented every six months. Clinically meaningful response to treatment is demonstrated in the following areas: Patient's quality of life including but not limited to level of independence and happiness; Patient's cognitive function including but not limited to memory, recognition and interest in environment; Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.	Compliance with Authority Required procedures - Streamlined Authority Code 13938
	C13940			Mild to moderately severe Alzheimer disease Initial Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs. Patients who qualify under this criterion are from 1 or more of the following groups: (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background; (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate; (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test; (4) Intellectual (developmental or acquired) disability, eg Down's syndrome; (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test; (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment. Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.	Compliance with Authority Required procedures

	C13941			Mild to moderately severe Alzheimer disease Initial Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified. Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.	Compliance with Authority Required procedures

[73] Schedule 4, Part 1, entry for Sacituzumab govitecan

(a) *omit from the column headed "Purposes Code" for the circumstance code "C12656":* **P12656**

(b) *omit from the column headed "Purposes Code" for the circumstance code "C12669":* **P12669**

(c) *omit:*

	C12670	P12670		Unresectable locally advanced or metastatic triple-negative breast cancer Transitioning from non-PBS to PBS-subsidised supply - Grandfather treatment Patient must must have received treatment with this drug for this PBS indication prior to 1 May 2022; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 1 prior to treatment initiation of non-PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this PBS indication.	Compliance with Authority Required procedures - Streamlined Authority Code 12670

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

(a) *insert after the entry for the circumstances code "C11956":*

	C11976			Moderate to severe ulcerative colitis Initial 1 (new patient) or 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 Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have 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	Compliance with Authority Required procedures

				The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	

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

	C13930	P13930		Moderate to severe ulcerative colitis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangementsr Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2023; AND Patient must be receiving treatment with this drug for this condition at the time of application; AND The condition must have responded inadequately to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for at least 3 consecutive months prior to treatment initiation with this drug; OR Patient must have experienced a severe intolerance to the above therapy leading to permanent treatment discontinuation; AND The condition must have responded inadequately to azathioprine at a dose of at least 2 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; OR The condition must have responded inadequately to 6-mercaptopurine at a dose of at least 1 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; OR The condition must have responded inadequately to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, followed by an inadequate response to at least 3 consecutive months of treatment with an appropriately dosed thiopurine agent, prior to treatment initiation with this drug; OR Patient must have experienced a severe intolerance to each of the above 3 therapies leading to permanent treatment discontinuation; AND Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing non-PBS-subsidised treatment with this drug for this condition; OR Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced non-PBS-subsidised treatment with this drug for this condition where a Mayo clinic or partial Mayo clinic baseline assessment is not available. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes: (i) the completed baseline Mayo clinic or partial Mayo clinic calculation sheet prior to initiating treatment (if available) including the date of assessment; (ii) the date of commencement of this drug. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. The assessment of the patient's response to this PBS-subsidised course of therapy must be conducted no later than 4 weeks	Compliance with Written Authority Required procedures

				from the cessation of the treatment course. 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. Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.	
	C13958	P13958		Moderate to severe ulcerative colitis Continuing treatment - balance of supply Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. The treatment must have been prescribed most recently through the Continuing treatment phase in a quantity which did not seek the full number available in regards to any of: (i) the quantity per dispensing, (ii) repeat prescriptions; AND The treatment must provide no more than the balance of 24 weeks treatment.	Compliance with Authority Required procedures
	C13959	P13959		Moderate to severe ulcerative colitis Dose modification Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND Patient must be undergoing existing PBS-subsidised treatment with this therapy.	Compliance with Authority Required procedures
	C13990			Moderate to severe ulcerative colitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; 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 a Mayo clinic score greater than or equal to 6; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score). Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and	Compliance with Written Authority Required procedures

				(ii) the details of prior biological medicine treatment including the details of date and duration of treatment. The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application. An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A maximum of 16 weeks of treatment with this drug will be approved under this criterion.	
	C13999			Moderate to severe ulcerative colitis Initial treatment - Initial 1 (new patient - untreated with biological medicine) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND Patient must have a Mayo clinic score greater than or equal to 6; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score). Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application. An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.	Compliance with Written Authority Required procedures

				Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. A maximum of 16 weeks of treatment with this drug will be approved under this criterion.	
	C14011	P14011		Moderate to severe ulcerative colitis Continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug. Patient must be at least 18 years of age. Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient 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.	Compliance with Authority Required procedures
	C14014			Moderate to severe ulcerative colitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR	Compliance with Written Authority Required procedures

				Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. 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. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. A maximum of 16 weeks of treatment with this drug will be approved under this criterion.	

[75] Schedule 4, Part 1, entry for Ustekinumab

insert in numerical order after existing text:

	C13927	P13927		Moderate to severe ulcerative colitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have 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 The treatment must not exceed a single dose to be administered at week 8 under this restriction. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and	Compliance with Written Authority Required procedures

				(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. 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. An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. A maximum of 16 weeks of treatment with this drug will be approved under this criterion. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats. Details of the accepted toxicities including severity can be found on the Services Australia website.	
	C13952	P13952		Moderate to severe ulcerative colitis Continuing treatment - balance of supply Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received insufficient therapy with this drug for this condition 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.	Compliance with Authority Required procedures
	C13955	P13955		Moderate to severe ulcerative colitis Initial treatment - initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; 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	Compliance with Written Authority Required procedures

				Patient must have a Mayo clinic score greater than or equal to 6; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); AND The treatment must not exceed a single dose to be administered at week 8 under this restriction. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to 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. An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A maximum of 16 weeks of treatment with this drug will be approved under this criterion. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats. Details of the accepted toxicities including severity can be found on the Services Australia website.	
	C13988	P13988		Moderate to severe ulcerative colitis Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or	Compliance with Written Authority Required procedures

				more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND Patient must have a Mayo clinic score greater than or equal to 6; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); AND The treatment must not exceed a single dose to be administered at week 8 under this restriction. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application. An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. A maximum of 16 weeks of treatment with this drug will be approved under this criterion. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.	
	C14009	P14009		Moderate to severe ulcerative colitis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2023;	Compliance with Written Authority Required procedures

				AND Patient must be receiving treatment with this drug for this condition at the time of application; AND The condition must have responded inadequately to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for at least 3 consecutive months prior to treatment initiation with this drug; OR Patient must have experienced a severe intolerance to the above therapy leading to permanent treatment discontinuation; AND The condition must have responded inadequately to azathioprine at a dose of at least 2 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; OR The condition must have responded inadequately to 6-mercaptopurine at a dose of at least 1 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; OR The condition must have responded inadequately to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, followed by an inadequate response to at least 3 consecutive months of treatment with an appropriately dosed thiopurine agent, prior to treatment initiation with this drug; OR Patient must have experienced a severe intolerance to each of the above 3 therapies leading to permanent treatment discontinuation; AND Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing non-PBS-subsidised treatment with this drug for this condition; OR Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced non-PBS-subsidised treatment with this drug for this condition where a Mayo clinic or partial Mayo clinic baseline assessment is not available; AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving 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. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes: (i) the completed baseline Mayo clinic or partial Mayo clinic calculation sheet prior to initiating treatment (if available) including the date of assessment; (ii) the date of commencement of this drug. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. The assessment of the patient's response to this PBS-subsidised course of therapy must be conducted no later than 4 weeks from the cessation of the treatment course. 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. Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.	

				At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.	
	C14018	P14018		Moderate to severe ulcerative colitis Continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving 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. Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient 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.	Compliance with Authority Required procedures

[76] Schedule 4, Part 1, after entry for Vorinostat

insert:

Vosoritide	C13929			achondroplasia Grandfather treatment (transition from non-PBS subsidised treatment) Patient must have a diagnosis of achondroplasia, confirmed by appropriate genetic testing; AND Patient must have received non-PBS subsidised vosoritide treatment for this condition prior to 1 May 2023; AND Patient must not have evidence of growth plate closure demonstrated by at least one of the following: i) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 6 months of this application if puberty has commenced; ii) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 2 years of commencing treatment if puberty has not	Compliance with Authority Required procedures

				commenced; iii) an annual growth velocity of greater than 1.5 cm/year as assessed over a period of at least 6 months. Must be treated by a medical specialist, experienced in the management of achondroplasia; OR Must be treated by a paediatrician in consultation with a medical specialist experienced in the management of achondroplasia. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised. Appropriate genetic testing constitutes testing for FGFR3 gene mutation. In patients where puberty has not commenced, radiographic evidence that epiphyses have not closed must be obtained within 2 years of commencing treatment with vosoritide. X-rays and dates (date commenced treatment and date of X-ray) must be documented in the patient's medical records. Additional radiographic evidence is not required until patient has begun puberty. In patients where puberty has commenced, radiographic evidence that epiphyses have not closed must be obtained within 6 months of completing an authority application for vosoritide. X-ray and date taken must be documented in the patient's medical records.	
	C13977			achondroplasia Initial treatment Patient must have a diagnosis of achondroplasia, confirmed by appropriate genetic testing; AND Patient must not have evidence of growth plate closure demonstrated by at least one of the following: i) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 6 months of this application if puberty has commenced; ii) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 2 years of commencing treatment if puberty has not commenced; iii) an annual growth velocity of greater than 1.5 cm/year as assessed over a period of at least 6 months. Must be treated by a medical specialist, experienced in the management of achondroplasia; OR Must be treated by a paediatrician in consultation with a medical specialist experienced in the management of achondroplasia. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised. Appropriate genetic testing constitutes testing for FGFR3 gene mutation. In patients where puberty has not commenced, radiographic evidence that epiphyses have not closed must be obtained within 2 years of commencing treatment with vosoritide. X-rays and dates (date commenced treatment and date of X-ray) must be documented in the patient's medical records. Additional radiographic evidence is not required until patient has begun puberty. In patients where puberty has commenced, radiographic evidence that epiphyses have not closed must be obtained within 6 months of completing an authority application for vosoritide. X-ray and date taken must be documented in the patient's medical records.	Compliance with Authority Required procedures
	C13998			achondroplasia Continuing treatment Patient must have received PBS subsidised vosoritide treatment for this condition; AND Patient must not have evidence of growth plate closure demonstrated by at least one of the following: i) bilateral lower	Compliance with Authority Required procedures

				extremity X-rays (proximal tibia, distal femur) taken within 6 months of this application if puberty has commenced; ii) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 2 years of commencing treatment if puberty has not commenced; iii) an annual growth velocity of greater than 1.5 cm/year as assessed over a period of at least 6 months. Must be treated by a medical specialist, experienced in the management of achondroplasia; OR Must be treated by a paediatrician in consultation with a medical specialist experienced in the management of achondroplasia. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised. In patients where puberty has not commenced, radiographic evidence that epiphyses have not closed must be obtained within 2 years of commencing treatment with vosoritide. X-rays and dates (date commenced treatment and date of X-ray) must be documented in the patient's medical records. Additional radiographic evidence is not required until patient has begun puberty. In patients where puberty has commenced, radiographic evidence that epiphyses have not closed must be obtained within 6 months of completing an authority application for vosoritide. X-ray and date taken must be documented in the patient's medical records.	