PB 1 of 2023

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 1)

National Health Act 1953

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

Dated 30 January 2023

NIKOLAI TSYGANOV
Assistant Secretary (Acting)
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. 1)*.

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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

omit from the column headed "Circumstances": **C12501**

[2] Schedule 1, Part 1, entry for Acarbose in the form Tablet 100 mg

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

		a	Acarbose Viatris	AL	MP NP			90	5	90

[3] Schedule 1, Part 1, entry for Ambrisentan in the form Tablet 10 mg

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

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

[4] Schedule 1, Part 1, after entry for Beclometasone with formoterol in the form Pressurised inhalation containing beclometasone dipropionate 100 micrograms and formoterol fumarate dihydrate 6 micrograms per dose,120 dose

insert:

	Pressurised inhalation containing beclometasone dipropionate 200 micrograms and formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	Fostair 200/6	EU	MP NP	C11057		1	5	1

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

(a) *insert in the column headed "Schedule Equivalent" for the brand "Neo-Mercazole":* **a**

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

		a	WP Carbimazole	TN	MP NP			200	2	100

[6] Schedule 1, Part 1, entry for Cinacalcet in the form Tablet 60 mg (as hydrochloride) *[Maximum Quantity: 28; Number of Repeats: 5]*

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

	a	Cinacalcet Viatris	AL	MP NP	C10068	28	5	28	

[7] **Schedule 1, Part 1, entry for Cinacalcet in the form Tablet 60 mg (as hydrochloride)** ***[Maximum Quantity: 56; Number of Repeats: 5]***

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

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

[8] **Schedule 1, Part 1, entry for Dimethyl fumarate in the form Capsule (modified release) 120 mg**

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

	a	APO-DIMETHYL FUMARATE	XT	MP	C10139 C10140	28	0	14	

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

	a	Dimethyl Fumarate MSN	LR	MP	C10139 C10140	28	0	14	

[9] **Schedule 1, Part 1, entry for Dimethyl fumarate in the form Capsule (modified release) 240 mg**

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

	a	APO-DIMETHYL FUMARATE	XT	MP	C10139	56	5	56	

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

	a	Dimethyl Fumarate MSN	LR	MP	C10139	56	5	56	

[10] **Schedule 1, Part 1, entry for Domperidone**

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

	a	APO-DOMPERIDONE	TX	MP NP		25	0	25	

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

[11] **Schedule 1, Part 1, omit entry for Exenatide**

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

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

		a	Fynod	AF	MP	C10162 C10172		28	5	28

[13] Schedule 1, Part 1, entry for Flucloxacillin in the form Capsule 250 mg (as sodium monohydrate)

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

		a	Flopen Viatris	MQ	MP NP MW	C5414		24	0	24
					PDP	C5298		24	0	24

[14] Schedule 1, Part 1, entry for Flucloxacillin in the form Capsule 500 mg (as sodium monohydrate) *[Maximum Quantity: 24; Number of Repeats: 0]*

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

		a	Flopen Viatris	MQ	MP	C5414 C6169	P5414	24	0	24
					NP MW	C5414		24	0	24
					PDP	C5298		24	0	24

[15] Schedule 1, Part 1, entry for Flucloxacillin in the form Capsule 500 mg (as sodium monohydrate) *[Maximum Quantity: 48; Number of Repeats: 1]*

(a) *omit from the column headed "Responsible Person" for the brand "Flopen":* **AS** *substitute:* **AL**

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

		a	Flopen Viatris	MQ	MP	C5414 C6169	P6169	48	1	24

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

substitute:

Lenalidomide	Capsule 5 mg	Oral	Cipla Lenalidomide	LR	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
					MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)

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

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

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

					MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
			Lenalidomide-Teva	TB	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
					MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
					MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
			Revlimid	CJ	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
					MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
					MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
Capsule 25 mg		Oral	Cipla Lenalidomide	LR	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
					MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
			Lenalide	JU	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
					MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
			Lenalidomide Dr.Reddy's	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
					MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
			Lenalidomide Sandoz	SZ	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
					MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)

	Lenalidomide-Teva	TB	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
			MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
	Revlimid	CJ	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
			MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)

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

(a) *omit from the column headed "Circumstances":* **C13760**

(b) *insert in numerical order in the column headed "Circumstances":* **C13824**

[18] Schedule 1, Part 1, entry for Morphine in the form Oral solution containing morphine hydrochloride trihydrate 2 mg per mL, 200 mL

substitute:

	Oral solution containing morphine hydrochloride trihydrate 2 mg per mL, 1 mL	Oral	Ordine 2	MF	MP NP	C10764 C10770 C10777		200	0	200
					PDP	C10859		200	0	200

[19] Schedule 1, Part 1, entry for Morphine in the form Oral solution containing morphine hydrochloride trihydrate 5 mg per mL, 200 mL

substitute:

	Oral solution containing morphine hydrochloride trihydrate 5 mg per mL, 1 mL	Oral	Ordine 5	MF	MP NP	C10764 C10770 C10777 C11697	P10764 P10770 P10777	200	0	200
					PDP	C10859		200	0	200
					MP NP	C10764 C10770 C10777 C11697	P11697	400	1	200

[20] Schedule 1, Part 1, entry for Morphine in the form Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 200 mL

substitute:

	Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL	Oral	Ordine 10	MF	MP NP	C10764 C10770 C10777 C11697	P10764 P10770 P10777	200	0	200
					PDP	C10859		200	0	200
					MP NP	C10764 C10770 C10777 C11697	P11697	400	1	200

[21] Schedule 1, Part 1, entry for Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Danish 1331 strain

omit from the column headed "Brand": **BCG Culture SSI** *substitute:* **VesiCulture**

[22] Schedule 1, Part 1, entry for Nirmatrelvir and ritonavir

(a) *omit from the column headed "Circumstances":* **C13760**

(b) *insert in numerical order in the column headed "Circumstances":* **C13821**

[23] Schedule 1, Part 1, entry for Nitrofurantoin in each of the forms: Capsule 50 mg; and Capsule 100 mg

omit:

			a	ARX-Nitrofurantoin	XT	MP NP MW		30	1	30

[24] Schedule 1, Part 1 after entry for Ondansetron in the form Wafer 8 mg

insert:

Opicapone	Capsule 50 mg	Oral	Ongentys	XY	MP NP	C5133		30	5	30

[25] Schedule 1, Part 1 entry for Oxycodone in the form Oral solution containing oxycodone hydrochloride 1 mg per mL, 250 mL

substitute:

	Oral solution containing oxycodone hydrochloride 1 mg per mL, 1 mL	Oral	OxyNorm Liquid 1mg/mL	MF	PDP	C10768		250	0	250
					MP NP	C10764 C10771 C10772		250	0	250

[26] Schedule 1, Part 1, entry for Polyethylene glycol 400 with propylene glycol

substitute:

Polyethylene glycol 400 with propylene glycol	Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 28	Application to the eye		Systane	AQ	AO MP NP	C6172		2	5	1
	Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 30	Application to the eye		Systane	AQ	AO MP NP	C6172		2	5	1
	Eye drops 4 mg-3 mg per mL, 15 mL	Application to the eye	a	Optix	PP	AO	C6120		1	5	1
						MP	C6073 C6098	P6073	1	5	1
						NP	C6073		1	5	1
			a	Systane	AQ	AO	C6120		1	5	1
						MP	C6073 C6098	P6073	1	5	1
						NP	C6073		1	5	1
			a	Optix	PP	MP	C6073 C6098	P6098	1	11	1
			a	Systane	AQ	MP	C6073 C6098	P6098	1	11	1

[27] Schedule 1, Part 1, entry for Romosozumab

omit from the column headed "Circumstances": **C11496 C12475** *substitute:* **C13819 C13820**

[28] Schedule 1, Part 1, entry for Salbutamol in the form Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 30

omit:

				APO-Salbutamol	TX	MP NP	C6815 C6825		2	5	1

[29] Schedule 1, Part 1, entry for Sitagliptin in each of the forms: Tablet 25 mg; Tablet 50 mg; and Tablet 100 mg

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

			a	Sitaglo	CR	MP	C6346 C6363 C6376 C7505 C7541		28	5	28
						NP	C6346 C6363 C6376 C7505		28	5	28

[30] Schedule 1, Part 1, entry for Sumatriptan in the form Tablet (fast disintegrating) 50 mg (as succinate)

substitute:

	Tablet (fast disintegrating) 50 mg (as succinate)	Oral	Imigran FDT	AS	MP NP	C5259		4	5	4

[31] Schedule 1, Part 1, entry for Temozolomide in the form Capsule 5 mg *[Maximum Quantity: 5; Number of Repeats: 5]*

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

		a	Temizole 5	AL	MP			5	5	5

(b) *omit:*

		a	Temozolomide Alphapharm	AF	MP			5	5	5

[32] Schedule 1, Part 1, entry for Temozolomide in the form Capsule 5 mg *[Maximum Quantity: 15; Number of Repeats: 2]*

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

		a	Temizole 5	AL	MP	P4897		15	2	5

(b) *omit:*

		a	Temozolomide Alphapharm	AF	MP	P4897		15	2	5

[33] Schedule 1, Part 1, entry for Tenecteplase in the form Powder for injection 50 mg with solvent (s19A)

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

			TNKase (Canada) Medsurge Healthcare Pty Ltd	DZ	MP NP	C5783		1	0	1

[34] Schedule 1, Part 1, entry for Tenofovir with emtricitabine and efavirenz

(a) *insert in the column headed "Schedule Equivalent" for the brand "Tenofovir Disoproxil/Emtricitabine/Efavirenz Mylan 300/200/600":* **a**

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

	a	Tenofovir Disoproxil Emtricitabine Efavirenz Viatris 300/200/600	AL	MP NP	C4470 C4522	60	5	30	D(100)

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

(a) *insert in the column headed "Schedule Equivalent" for the brand "iNova Pharmaceuticals (Australia) Pty Ltd":* **a**

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

	a	Tetrabenazine SUN	RA	MP NP	C5340	112	5	112	

[36] Schedule 1, Part 1, entry for Tobramycin in the form Injection 80 mg in 2 mL

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

	a	Tobramycin Viatris	AL	MP NP	C5446 C5490 C5519	10	1	5	

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

(a) *omit from the column headed "Circumstances":* **C12496**

(b) *omit from the column headed "Circumstances":* **C12502**

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

(a) *omit from the column headed "Circumstances":* **C12496**

(b) *omit from the column headed "Circumstances":* **C12502**

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

(a) *omit from the column headed "Circumstances":* **C12496**

(b) *omit from the column headed "Circumstances":* **C12502**

(c) *omit from the column headed "Purposes":* **P12496 P12502**

[40] Schedule 1, Part 1, entry for Upadacitinib in the form Tablet 30 mg *[Maximum Quantity: 28; Number of Repeats: 3]*

(a) *omit from the column headed "Circumstances":* **C12496**

(b) *omit from the column headed "Circumstances":* **C12502**

[41] **Schedule 1, Part 1, entry for Upadacitinib in the form Tablet 30 mg *[Maximum Quantity: 28; Number of Repeats: 4]***

(a) *omit from the column headed "Circumstances":* **C12496**

(b) *omit from the column headed "Circumstances":* **C12502**

[42] **Schedule 1, Part 1, entry for Upadacitinib in the form Tablet 30 mg *[Maximum Quantity: 28; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C12496**

(b) *omit from the column headed "Circumstances":* **C12502**

(c) *omit from the column headed "Purposes":* **P12496 P12502**

[43] **Schedule 1, Part 1, entry for Vancomycin in the form Capsule 125 mg (125,000 I.U.) (as hydrochloride)**

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

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

	a	Vancomycin BNM 125mg	BZ	MP	C5636 C5660	40	0	20

[44] **Schedule 1, Part 1, entry for Vancomycin in the form Capsule 250 mg (250,000 I.U.) (as hydrochloride)**

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

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

	a	Vancomycin BNM 250mg	BZ	MP	C5636 C5660	40	0	20

[45] **Schedule 1, Part 2, omit entry for Amino acid formula with vitamins and minerals without phenylalanine**

[46] **Schedule 1, Part 2, entry for Cromoglycic acid**

omit:

Pressurised inhalation containing sodium cromoglycate 1 mg per dose, 200 doses (CFC-free formulation)	Inhalation by mouth	Intal CFC-Free	SW	MP NP		1	5	1

[47] **Schedule 1, Part 2, omit entry for Glycomacropeptide and essential amino acids with vitamins and minerals**

[48] **Schedule 1, Part 2, omit entry for Ledipasvir with sofosbuvir**

[49] Schedule 3, after details relevant for Responsible Person code TM

insert:

TN	Medtas Pty Ltd	72 644 270 860

[50] Schedule 3, after details relevant for Responsible Person code XW

insert:

XY	MAXX PHARMA PTY LTD	33 629 622 224

[51] Schedule 4, Part 1, entry for Acalabrutinib

omit:

	C12501			Mantle cell lymphoma Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have received treatment with this drug prior to 1 February 2022; AND The condition must have relapsed or be refractory to at least one prior therapy prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had a WHO performance status of 0 or 1 at the time non-PBS-subsidised treatment with this drug for this condition was initiated; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have been untreated with Bruton's tyrosine kinase inhibitor therapy at treatment initiation with this drug; OR Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication; AND Patient must not have developed disease progression while being treated with this drug for this condition.	Compliance with Authority Required procedures

[52] Schedule 4, Part 1, omit entry for Exenatide

[53] Schedule 4, Part 1, omit entry for Ledipasvir with sofosbuvir

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

(a) *omit:*

	C13760			SARS-CoV-2 infection Patient must have received a positive polymerase chain reaction (PCR) test result; OR Patient must have received a positive rapid antigen test (RAT) result; AND Patient must have at least one sign or symptom attributable to COVID-19; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND Patient must be moderately to severely immunocompromised; AND Patient must be at risk of progression to severe disease due to immunocompromised status; AND The treatment must be initiated within 5 days of symptom onset.	Compliance with Authority Required procedures - Streamlined Authority Code 13760

				Patient must be at least 18 years of age. For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with: 1. Any primary or acquired immunodeficiency including: a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders, b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months), c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR 2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received: a. Chemotherapy or whole body radiotherapy, b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy, c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin), d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR 3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR 4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR 5. People with disability with multiple comorbidities and/or frailty. Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell. Access to this drug through this restriction is permitted irrespective of vaccination status. Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record. Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record. This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.	

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

	C13824			SARS-CoV-2 infection Patient must have received a positive polymerase chain reaction (PCR) test result; OR Patient must have received a positive rapid antigen test (RAT) result; AND Patient must have at least one sign or symptom attributable to COVID-19; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND Patient must satisfy at least one of the following criteria: (i) be moderately to severely immunocompromised with risk of progression to severe COVID-19 disease due to the immunocompromised status, (ii) has experienced past COVID-19 infection resulting in hospitalisation; AND The treatment must be initiated within 5 days of symptom onset.	Compliance with Authority Required procedures - Streamlined Authority Code 13824

				Patient must be at least 18 years of age. For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with: 1. Any primary or acquired immunodeficiency including: a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders, b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months), c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR 2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received: a. Chemotherapy or whole body radiotherapy, b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy, c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin), d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR 3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR 4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR 5. People with disability with multiple comorbidities and/or frailty. Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell. Access to this drug through this restriction is permitted irrespective of vaccination status. Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record. Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record. This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.	

[55] Schedule 4, Part 1, entry for Nirmatrelvir and ritonavir

(a) *omit:*

	C13760			SARS-CoV-2 infection Patient must have received a positive polymerase chain reaction (PCR) test result; OR Patient must have received a positive rapid antigen test (RAT) result; AND Patient must have at least one sign or symptom attributable to COVID-19; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND Patient must be moderately to severely immunocompromised; AND Patient must be at risk of progression to severe disease due to immunocompromised status; AND	Compliance with Authority Required procedures - Streamlined Authority Code 13760

				The treatment must be initiated within 5 days of symptom onset. Patient must be at least 18 years of age. For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with: 1. Any primary or acquired immunodeficiency including: a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders, b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months), c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR 2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received: a. Chemotherapy or whole body radiotherapy, b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy, c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin), d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR 3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR 4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR 5. People with disability with multiple comorbidities and/or frailty. Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell. Access to this drug through this restriction is permitted irrespective of vaccination status. Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record. Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record. This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.	

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

	C13821			SARS-CoV-2 infection Patient must have received a positive polymerase chain reaction (PCR) test result; OR Patient must have received a positive rapid antigen test (RAT) result; AND Patient must have at least one sign or symptom attributable to COVID-19; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND Patient must satisfy at least one of the following criteria: (i) be moderately to severely immunocompromised with risk of progression to severe COVID-19 disease due to the immunocompromised status, (ii) has experienced past COVID-19 infection resulting in hospitalisation; AND	Compliance with Authority Required procedures - Streamlined Authority Code 13821

				The treatment must be initiated within 5 days of symptom onset. Patient must be at least 18 years of age. For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with: 1. Any primary or acquired immunodeficiency including: a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders, b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months), c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR 2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received: a. Chemotherapy or whole body radiotherapy, b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy, c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin), d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR 3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR 4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR 5. People with disability with multiple comorbidities and/or frailty. Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell. Access to this drug through this restriction is permitted irrespective of vaccination status. Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record. Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record. This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.	

[56] Schedule 4, Part 1, after entry for Ondansetron

insert:

Opicapone	C5133			Parkinson disease The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination; AND Patient must be experiencing fluctuations in motor function due to end-of-dose effect.	

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

substitute:

Romosozumab	C13819			Severe established osteoporosis Initial treatment Patient must be at very high risk of fracture; AND Patient must have a bone mineral density (BMD) T-score of -3.0 or less; AND Patient must have had 2 or more fractures due to minimal trauma; AND Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not exceed a lifetime maximum of 12 months therapy; AND Patient must not have received treatment with PBS-subsidised teriparatide; OR Patient must have developed intolerance to teriparatide of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy. Must be treated by a consultant physician. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with this drug is initiated. If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with this drug is initiated. Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum. Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.	Compliance with Authority Required procedures
	C13820			Severe established osteoporosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed a lifetime maximum of 12 months therapy. Must be treated by a medical practitioner identifying as either: (i) a consultant physician, (ii) a general practitioner.	Compliance with Authority Required procedures

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

(a) *omit:*

	C12496	P12496		Chronic severe atopic dermatitis Transitioning from non-PBS to PBS-subsidised supply (treatment of the face and/or hands) - Grandfather arrangements Patient must have been receiving treatment with this therapy for chronic severe atopic dermatitis prior to 1 February 2022; AND The condition must have had at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to commencing non-PBS-subsidised treatment with this therapy; OR The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to commencing non-PBS-subsidised treatment with this therapy; AND Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to having commenced non-PBS-subsidised treatment with this therapy; OR Patient must have, where the above baseline DLQI was not recorded in the patient's medical records, a current age-appropriate DLQI score (of any value) measured; AND The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, prior to commencing non-PBS-subsidised treatment with this therapy; AND Patient must not be experiencing an inadequate response to non-PBS-subsidised treatment with this therapy; AND Patient must not have experienced an inadequate response to this therapy in this indication, prior to commencing non-PBS-subsidised treatment with this therapy. Must be treated by a dermatologist; OR Must be treated by a clinical immunologist; AND Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis). Patient must be 12 years of age or older. State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for: (i) erythema, (ii) oedema/papulation, (iii) excoriation, (iv) lichenification Acceptable scores can be: (a) current scores; or (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication. State the percentage face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores. The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records. Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records.	Compliance with Written Authority Required procedures

				A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.	

(b) *omit:*

	C12502	P12502		Chronic severe atopic dermatitis Transitioning from non-PBS to PBS-subsidised supply (treatment of the whole body) - Grandfather arrangements Patient must have been receiving treatment with this therapy for chronic severe atopic dermatitis prior to 1 February 2022; AND Patient must have had a Physicians Global Assessment (PGA) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days prior to commencing non-PBS-subsidised treatment with this therapy; AND Patient must have had an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days prior to having commenced non-PBS-subsidised treatment with this therapy; AND Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to having commenced non-PBS-subsidised treatment with this therapy; OR Patient must have, where the above baseline DLQI was not recorded in the patient's medical records, a current age-appropriate DLQI score (of any value) measured; AND The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, prior to commencing non-PBS-subsidised treatment with this therapy; AND Patient must not be experiencing an inadequate response to non-PBS-subsidised treatment with this therapy; AND Patient must not have experienced an inadequate response to this therapy in this indication, prior to commencing non-PBS-subsidised treatment with this therapy. Must be treated by a dermatologist; OR Must be treated by a clinical immunologist; AND Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis). Patient must be 12 years of age or older. State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application. Acceptable scores can be: (a) current scores; or (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication. The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records. Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records. A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.	Compliance with Written Authority Required procedures

[59] Schedule 4, Part 3, General statement for drugs for the treatment of hepatitis C

substitute:

Part 3—General statement for drugs for the treatment of hepatitis C

1 Criteria for eligibility for drugs for the treatment of chronic hepatitis C

The criteria for patient eligibility for drugs for the treatment of chronic hepatitis C are that:

(1) the patient has been assessed in accordance with paragraph 2 of this Part; and

(2) the patient is:

(a) treated by a medical practitioner or an authorised nurse practitioner who is experienced in the treatment of patients with chronic hepatitis C infection; or

(b) treated by a medical practitioner or an authorised nurse practitioner in consultation with:

(i) a gastroenterologist; or

(ii) a hepatologist; or

(iii) an infectious diseases physician.

2 Assessment of patient

For the purpose of subparagraph 1(2) of this Part, the patient has been assessed if the treating medical practitioner has:

(1) documented the following information in the patient's medical records:

(a) evidence of chronic hepatitis C infection; and

(b) where possible, evidence of the patient's hepatitis C virus genotype; and

(2) chosen a regimen in accordance with paragraph 3 of this Part; and

(3) collected the following information for the purposes of the authority application:

(a) whether the patient is:

(i) cirrhotic; or
(ii) non-cirrhotic

(b) details of the previous treatment regimen (**only** for requests for sofosbuvir with velpatasvir and voxilaprevir or glecaprevir with pibrentasvir for treatment in patients who have previously failed a treatment with a regimen containing an NS5A inhibitor).

(4) In this paragraph, evidence of chronic hepatitis C infection is documentation of:
(a) repeat test results showing antibody to hepatitis C virus (anti-HCV) positive; and
(b) test result showing hepatitis C virus ribonucleic acid (RNA) positive.

3 Treatment regimen

For the purpose of subparagraph 2(2) of this Part, the treating medical practitioner has chosen a regimen in accordance with this paragraph if the patient:

(1) is a kind of patient mentioned for an Item in column 2 of the following table; and

(2) is to receive one of the regimens mentioned in column 3 of the same Item of the following table.

Item	Kind of patient	Regimen
1	Patient: (a) all genotypes (pan-genotypic); and (b) who is treatment naïve; and (c) who is non-cirrhotic.	Either: (a) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (b) GLECAPREVIR with PIBRENTASVIR for 8 weeks.
2	Patient: (a) all genotypes (pan-genotypic); and (b) who is treatment experienced; and (c) who is non-cirrhotic.	Either: (a) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (b) SOFOSBUVIR with VELPATASVIR and VOXILAPREVIR for 12 weeks; or (c) GLECAPREVIR with PIBRENTASVIR for 8 weeks; or (d) GLECAPREVIR with PIBRENTASVIR for 12 weeks; or

Item	Kind of patient	Regimen
		(e) GLECAPREVIR with PIBRENTASVIR 16 weeks.
3	Patient: (a) with Genotype 1; and (b) who is treatment naïve; and (c) who is non-cirrhotic.	Refer to item 1 above (pan-genotypic, treatment naïve and non-cirrhotic regimens).
4	Patient: (a) with Genotype 1; and (b) who is treatment experienced; and (c) who is non-cirrhotic.	Refer to item 2 above (pan-genotypic, treatment experienced and non-cirrhotic regimens).
5	Patient: (a) with Genotype 2; and (b) who is treatment naïve; and (c) who is non-cirrhotic.	Refer to item 1 above (pan-genotypic, treatment naïve and non-cirrhotic regimens).
6	Patient: (a) with Genotype 2; and (b) who is treatment experienced; and (c) who is non-cirrhotic.	Refer to item 2 above (pan-genotypic, treatment experienced and non-cirrhotic regimens).
7	Patient: (a) with Genotype 3; and (b) who is treatment naïve; and (c) who is non-cirrhotic.	Refer to item 1 above (pan-genotypic, treatment naïve and non-cirrhotic regimens).
8	Patient: (a) with Genotype 3; and	Refer to item 2 above (pan-genotypic, treatment experienced and non-cirrhotic regimens).

Item	Kind of patient	Regimen
	(b) who is treatment experienced; and (c) who is non-cirrhotic.	
9	Patient: (a) with Genotype 4; and (b) who is treatment naïve; and (c) who is non-cirrhotic.	Refer to item 1 above (pan-genotypic, treatment naïve and non-cirrhotic regimens).
10	Patient: (a) with Genotype 4; and (b) who is treatment experienced; and (c) who is non-cirrhotic.	Refer to item 2 above (pan-genotypic, treatment experienced and non-cirrhotic regimens).
11	Patient: (a) with: (i) Genotype 5; or (ii) Genotype 6; and (b) who is treatment naïve; and (c) who is non-cirrhotic.	Refer to item 1 above (pan-genotypic, treatment naïve and non-cirrhotic regimens).
12	Patient: (a) with: (i) Genotype 5; or (ii) Genotype 6; and (b) who is treatment experienced; and (c) who is non-cirrhotic.	Refer to item 2 above (pan-genotypic, treatment experienced and non-cirrhotic regimens).
13	Patient:	Either:

Item	Kind of patient	Regimen
	(a) all genotypes (pan-genotypic); and (b) who is treatment naïve; and (c) who is cirrhotic.	(a) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (b) GLECAPREVIR with PIBRENTASVIR for 8 weeks; or (c) GLECAPREVIR with PIBRENTASVIR for 12 weeks
14	Patient: (a) all genotypes (pan-genotypic); and (b) who is treatment experienced; and (c) who is cirrhotic.	Either: (a) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (b) SOFOSBUVIR with VELPATASVIR and VOXILAPREVIR for 12 weeks; or (c) GLECAPREVIR with PIBRENTASVIR for 12 weeks; or (d) GLECAPREVIR with PIBRENTASVIR for 16 weeks.
15	Patient: (a) with Genotype 1; and (b) who is treatment naïve; and (c) who is cirrhotic.	Refer to item 13 above (pan-genotypic, treatment naïve and cirrhotic regimens).
16	Patient: (a) with Genotype 1; and (b) who is treatment experienced; and (c) who is cirrhotic.	Refer to item 14 above (pan-genotypic, treatment experienced and cirrhotic regimens).
17	Patient: (a) with Genotype 2; and (b) who is treatment naïve; and (c) who is cirrhotic.	Refer to item 13 above (pan-genotypic, treatment naïve and cirrhotic regimens).
18	Patient: (a) with Genotype 2; and (b) who is treatment experienced; and	Refer to item 14 above (pan-genotypic, treatment experienced and cirrhotic regimens).

Item	Kind of patient	Regimen
	(c) who is cirrhotic.	
19	Patient: (a) with Genotype 3; and (b) who is treatment naïve; and (c) who is cirrhotic.	Refer to item 13 above (pan-genotypic, treatment naïve and cirrhotic regimens).
20	Patient: (a) with Genotype 3; and (b) who is treatment experienced; and (c) who is cirrhotic.	Refer to item 14 above (pan-genotypic, treatment experienced and cirrhotic regimens).
21	Patient: (a) with Genotype 4; and (b) who is treatment naïve; and (c) who is cirrhotic.	Refer to item 13 above (pan-genotypic, treatment naïve and cirrhotic regimens).
22	Patient: (a) with Genotype 4; and (b) who is treatment experienced; and (c) who is cirrhotic.	Refer to item 14 above (pan-genotypic, treatment experienced and cirrhotic regimens).
23	Patient: (a) with: (i) Genotype 5; or (ii) Genotype 6; and (b) who is treatment naïve; and (c) who is cirrhotic.	Refer to item 13 above (pan-genotypic, treatment naïve and cirrhotic regimens).

Item	Kind of patient	Regimen
24	Patient: (a) with: (i) Genotype 5; or (ii) Genotype 6; and (b) who is treatment experienced; and (c) who is cirrhotic.	Refer to item 14 above (pan-genotypic, treatment experienced and cirrhotic regimens).

[60] **Schedule 5, entry for Salbutamol in the form Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 30 [*GRP-21361*]**

omit from the column headed "Brand": **APO-Salbutamol**

[61] **Schedule 5, entry for Tenecteplase in the form Powder for injection 50 mg with solvent (s19A)**

insert in alphabetical order in the column headed "Brand": **TNKase (Canada) Medsurge Healthcare Pty Ltd**