PB 95 of 2024

National Health (Listing of Pharmaceutical Benefits) Amendment (October Update) Instrument 2024

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 September 2024

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

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Schedule 1—Amendments 1

National Health (Listing of Pharmaceutical Benefits) Instrument 2024 (PB 26 of 2024). 2

1 Name

(1) This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (October Update) Instrument 2024*.

(2) This Instrument may also be cited as PB 95 of 2024.

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 October 2024*	*1 October 2024*

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 2024 (PB 26 of 2024)

[1] Schedule 1, Part 1, entry for Abacavir with lamivudine

omit:

Abacavir with lamivudine	Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg	Oral	ABACAVIR/LAMIVUDINE 600/300 SUN	RA	MP NP	C4527 C4528		60	5	30	D(100)

[2] Schedule 1, Part 1, after entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Brand: Adalicip; Maximum Quantity: 6; Number of Repeats: 0]*

insert:

Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hadlima	OQ	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hadlima	OQ	MP	C12120 C14061 C14063 C14064 C14107 C14136	See Note 3	See Note 3	See Note 3	2	C(100)
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hadlima	OQ	MP	C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hadlima	OQ	MP	C9064 C9386 C11861 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672	2	3	2	

						C14673	P14673			
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hadlima	OQ	MP	C11107 C12155 C12212 C13556 C13612 C14377 C14378	P11107 P12155 P12212 P13556 P13612 P14377 P14378	2	4	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hadlima	OQ	MP	C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11711 C11717 C11718 C11767 C11853 C11865 C11867 C11903 C11906 C11966 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C15450	P11523 P11524 P11579 P11604 P11606 P11631 P11635 P11704 P11711 P11717 P11718 P11767 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P15450	2	5	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hadlima	OQ	MP	C15474 C15489	P15474 P15489	2	6	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hadlima	OQ	MP	C15788	P15788	4	2	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hadlima	OQ	MP	C11529 C15777 C15796	P11529 P15777 P15796	4	5	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hadlima	OQ	MP	C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147	6	0	2

							C13602 C13609 C15764 C15765 C15795	P13602 P13609 P15764 P15765 P15795				

[3] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Adalicip; Maximum Quantity: 2; Number of Repeats: 0]***

(a) *insert in numerical order in the column headed "Circumstances":* **C15473**

(b) *insert in numerical order in the column headed "Purposes":* **P15473**

[4] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Adalicip; Maximum Quantity: 2; Number of Repeats: 5]***

(a) *insert in numerical order in the column headed "Circumstances":* **C15445 C15446 C15450**

(b) *insert in numerical order in the column headed "Purposes":* **P15445 P15446 P15450**

[5] **Schedule 1, Part 1, after entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Adalicip; Maximum Quantity: 2; Number of Repeats: 5]***

insert:

Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Adalicip	LR	MP	C15474 C15489	P15474 P15489	2	6	2	

[6] **Schedule 1, Part 1, after entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Adalicip; Maximum Quantity: 6; Number of Repeats: 0]***

insert:

Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hadlima	OQ	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hadlima	OQ	MP	C12120 C14061 C14063 C14064 C14107 C14136	See Note 3	See Note 3	See Note 3	2	C(100)
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hadlima	OQ	MP	C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098	2	2	2	

						C12101 C12147 C13602 C13609	P12101 P12147 P13602 P13609			
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hadlima	OQ	MP	C9064 C9386 C11861 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673	2	3	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hadlima	OQ	MP	C11107 C12155 C12212 C13556 C13612 C14377 C14378	P11107 P12155 P12212 P13556 P13612 P14377 P14378	2	4	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hadlima	OQ	MP	C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11711 C11717 C11718 C11767 C11853 C11865 C11867 C11903 C11906 C11966 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C15450	P11523 P11524 P11579 P11604 P11606 P11631 P11635 P11704 P11711 P11717 P11718 P11767 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P15450	2	5	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hadlima	OQ	MP	C15474 C15489	P15474 P15489	2	6	2

Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hadlima	OQ	MP	C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	6	0	2

[7] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Humira; Maximum Quantity: 2; Number of Repeats: 0]***

(a) *insert in numerical order in the column headed "Circumstances":* **C15473**

(b) *insert in numerical order in the column headed "Purposes":* **P15473**

[8] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Humira; Maximum Quantity: 2; Number of Repeats: 5]***

(a) *insert in numerical order in the column headed "Circumstances":* **C15446 C15450**

(b) *insert in numerical order in the column headed "Purposes":* **P15446 P15450**

[9] **Schedule 1, Part 1, after entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Humira; Maximum Quantity: 2; Number of Repeats: 5]***

insert:

Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Humira	VE	MP	C15474 C15489	P15474 P15489	2	6	2

[10] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Yuflyma; Maximum Quantity: 2; Number of Repeats: 0]***

(a) *insert in numerical order in the column headed "Circumstances":* **C15473**

(b) *insert in numerical order in the column headed "Purposes":* **P15473**

[11] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Yuflyma; Maximum Quantity: 2; Number of Repeats: 5]***

(a) *insert in numerical order in the column headed "Circumstances":* **C15445 C15446 C15450**

(b) *insert in numerical order in the column headed "Purposes":* **P15445 P15446 P15450**

[12] Schedule 1, Part 1, after entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Yuflyma; Maximum Quantity: 2; Number of Repeats: 5]*

insert:

Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Yuflyma	EW	MP	C15474 C15489	P15474 P15489	2	6	2	

[13] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen

omit:

Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Idacio	PK	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Idacio	PK	MP	C12120 C14061 C14063 C14064 C14107 C14136	See Note 3	See Note 3	See Note 3	2	C(100)
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Idacio	PK	MP	C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Idacio	PK	MP	C9064 C9386 C11861 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673	2	3	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Idacio	PK	MP	C11107 C12155 C12212 C13556 C13612 C14377 C14378	P11107 P12155 P12212 P13556 P13612 P14377 P14378	2	4	2	

Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Idacio	PK	MP	C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11711 C11717 C11718 C11767 C11853 C11865 C11867 C11903 C11906 C11966 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C15450	P11523 P11524 P11579 P11604 P11606 P11631 P11635 P11704 P11711 P11717 P11718 P11767 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P15450	2	5	2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Idacio	PK	MP	C15474 C15489	P15474 P15489	2	6	2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Idacio	PK	MP	C15788	P15788	4	2	2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Idacio	PK	MP	C11529 C15777 C15796	P11529 P15777 P15796	4	5	2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Idacio	PK	MP	C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609 C15764 C15765 C15795	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 P15764 P15765 P15795	6	0	2

[14] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe

omit:

Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Idacio	PK	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Idacio	PK	MP	C12120 C14061 C14063 C14064 C14107 C14136	See Note 3	See Note 3	See Note 3	2	C(100)
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Idacio	PK	MP	C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Idacio	PK	MP	C9064 C9386 C11861 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673	2	3	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Idacio	PK	MP	C11107 C12155 C12212 C13556 C13612 C14377 C14378	P11107 P12155 P12212 P13556 P13612 P14377 P14378	2	4	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Idacio	PK	MP	C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11711 C11717 C11718 C11767 C11853 C11865 C11867 C11903 C11906 C11966	P11523 P11524 P11579 P11604 P11606 P11631 P11635 P11704 P11711 P11717 P11718 P11767 P11853 P11865 P11867 P11903 P11906 P11966	2	5	2	

							C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C15450	P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P15450			
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Idacio	PK	MP	C15474 C15489	P15474 P15489	2	6	2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Idacio	PK	MP	C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	6	0	2

[15] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 80 mg in 0.8 mL pre-filled pen *[Brand: Humira; Maximum Quantity: 2; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15797** *substitute:* **C15777 C15796**

(b) *omit from the column headed "Purposes":* **P15797** *substitute:* **P15777 P15796**

[16] **Schedule 1, Part 1, after entry for Adalimumab in the form Injection 80 mg in 0.8 mL pre-filled pen *[Brand: Humira; Maximum Quantity: 3; Number of Repeats: 0]***

insert:

Adalimumab	Injection 80 mg in 0.8 mL pre-filled pen	Injection	Yuflyma	EW	MP	C12103 C12105 C12155 C12212 C14398 C14399	P12103 P12105 P12155 P12212 P14398 P14399	1	0	1
Adalimumab	Injection 80 mg in 0.8 mL pre-filled pen	Injection	Yuflyma	EW	MP	C15788	P15788	2	2	1

Adalimumab	Injection 80 mg in 0.8 mL pre-filled pen	Injection	Yuflyma	EW	MP	C11529 C15777 C15796	P11529 P15777 P15796	2	5	1
Adalimumab	Injection 80 mg in 0.8 mL pre-filled pen	Injection	Yuflyma	EW	MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12152 C12229 C15764 C15765 C15795	P11715 P11716 P11759 P11761 P11762 P11763 P11852 P11854 P11855 P12152 P12229 P15764 P15765 P15795	3	0	1

[17] Schedule 1, Part 1, entry for Adalimumab in the form Injection 80 mg in 0.8 mL pre-filled syringe *[Brand: Humira; Maximum Quantity: 2; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C15797** *substitute:* **C15777 C15796**

(b) *omit from the column headed "Purposes":* **P15797** *substitute:* **P15777 P15796**

[18] Schedule 1, Part 1, after entry for Adalimumab in the form Injection 80 mg in 0.8 mL pre-filled syringe *[Brand: Humira; Maximum Quantity: 3; Number of Repeats: 0]*

insert:

Adalimumab	Injection 80 mg in 0.8 mL pre-filled syringe	Injection	Yuflyma	EW	MP	C12103 C12105 C12155 C12212 C14398 C14399	P12103 P12105 P12155 P12212 P14398 P14399	1	0	1
Adalimumab	Injection 80 mg in 0.8 mL pre-filled syringe	Injection	Yuflyma	EW	MP	C15788	P15788	2	2	1
Adalimumab	Injection 80 mg in 0.8 mL pre-filled syringe	Injection	Yuflyma	EW	MP	C11529 C15777 C15796	P11529 P15777 P15796	2	5	1
Adalimumab	Injection 80 mg in 0.8 mL pre-filled syringe	Injection	Yuflyma	EW	MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12152 C12229 C15764 C15765 C15795	P11715 P11716 P11759 P11761 P11762 P11763 P11852 P11854 P11855 P12152 P12229 P15764 P15765 P15795	3	0	1

[19] Schedule 1, Part 1, after entry for Aflibercept in the form Solution for intravitreal injection 4 mg in 100 microlitres (40 mg per mL) *[Maximum Quantity: 1; Number of Repeats: 5]*

insert:

Aflibercept	Solution for intravitreal injection 11.43 mg in 100 microlitres (114.3 mg per mL)	Injection	Eylea	BN	MP	C13406 C15918 C15952	P13406 P15918 P15952	1	2	1
Aflibercept	Solution for intravitreal injection 11.43 mg in 100 microlitres (114.3 mg per mL)	Injection	Eylea	BN	MP	C13402 C15919 C15928	P13402 P15919 P15928	1	5	1

[20] Schedule 1, Part 1, entries for Amoxicillin in the form Capsule 250 mg (as trihydrate)

substitute:

Amoxicillin	Capsule 250 mg (as trihydrate)	Oral	Alphamox 250	AF	MP NP MW PDP			20	0	20
Amoxicillin	Capsule 250 mg (as trihydrate)	Oral	Alphamox 250	AF	MP NP		P10404	40 CN10404	0 CN10404	20
Amoxicillin	Capsule 250 mg (as trihydrate)	Oral	AMILOXYN	RF	MP NP MW PDP			20	0	20
Amoxicillin	Capsule 250 mg (as trihydrate)	Oral	AMILOXYN	RF	MP NP		P10404	40 CN10404	0 CN10404	20
Amoxicillin	Capsule 250 mg (as trihydrate)	Oral	Amoxil	AS	MP NP MW PDP			20	0	20
Amoxicillin	Capsule 250 mg (as trihydrate)	Oral	Amoxil	AS	MP NP		P10404	40 CN10404	0 CN10404	20
Amoxicillin	Capsule 250 mg (as trihydrate)	Oral	APO-Amoxycillin	TX	MP NP MW PDP			20	0	20

Amoxicillin	Capsule 250 mg (as trihydrate)	Oral	APO-Amoxycillin	TX	MP NP	P10404	40 CN10404	0 CN10404	20
Amoxicillin	Capsule 250 mg (as trihydrate)	Oral	Cilamox	AL	MP NP MW PDP		20	0	20
Amoxicillin	Capsule 250 mg (as trihydrate)	Oral	Cilamox	AL	MP NP	P10404	40 CN10404	0 CN10404	20

[21] Schedule 1, Part 1, entries for Amoxicillin in the form Capsule 500 mg (as trihydrate)

substitute:

Amoxicillin	Capsule 500 mg (as trihydrate)	Oral	Alphamox 500	AF	MP NP MW PDP		20	0	20
Amoxicillin	Capsule 500 mg (as trihydrate)	Oral	Alphamox 500	AF	MP NP	P10402	40 CN10402	0 CN10402	20
Amoxicillin	Capsule 500 mg (as trihydrate)	Oral	AMILOXYN	RF	MP NP MW PDP		20	0	20
Amoxicillin	Capsule 500 mg (as trihydrate)	Oral	AMILOXYN	RF	MP NP	P10402	40 CN10402	0 CN10402	20
Amoxicillin	Capsule 500 mg (as trihydrate)	Oral	AMOXICILLIN-WGR	WG	MP NP MW PDP		20	0	20
Amoxicillin	Capsule 500 mg (as trihydrate)	Oral	AMOXICILLIN-WGR	WG	MP NP	P10402	40 CN10402	0 CN10402	20
Amoxicillin	Capsule 500 mg (as trihydrate)	Oral	Amoxil	AS	MP NP MW PDP		20	0	20
Amoxicillin	Capsule 500 mg (as trihydrate)	Oral	Amoxil	AS	MP NP	P10402	40 CN10402	0 CN10402	20
Amoxicillin	Capsule 500 mg (as trihydrate)	Oral	Amoxycillin generichealth 500	GQ	MP NP MW		20	0	20

					PDP				
Amoxicillin	Capsule 500 mg (as trihydrate)	Oral	Amoxycillin generichealth 500	GQ	MP NP	P10402	40 CN10402	0 CN10402	20
Amoxicillin	Capsule 500 mg (as trihydrate)	Oral	Amoxycillin Sandoz	SZ	MP NP MW PDP		20	0	20
Amoxicillin	Capsule 500 mg (as trihydrate)	Oral	Amoxycillin Sandoz	SZ	MP NP	P10402	40 CN10402	0 CN10402	20
Amoxicillin	Capsule 500 mg (as trihydrate)	Oral	APO-Amoxycillin	TX	MP NP MW PDP		20	0	20
Amoxicillin	Capsule 500 mg (as trihydrate)	Oral	APO-Amoxycillin	TX	MP NP	P10402	40 CN10402	0 CN10402	20
Amoxicillin	Capsule 500 mg (as trihydrate)	Oral	Blooms The Chemist Amoxicillin	BG	MP NP MW PDP		20	0	20
Amoxicillin	Capsule 500 mg (as trihydrate)	Oral	Blooms The Chemist Amoxicillin	BG	MP NP	P10402	40 CN10402	0 CN10402	20
Amoxicillin	Capsule 500 mg (as trihydrate)	Oral	Cilamox	AL	MP NP MW PDP		20	0	20
Amoxicillin	Capsule 500 mg (as trihydrate)	Oral	Cilamox	AL	MP NP	P10402	40 CN10402	0 CN10402	20

[22] Schedule 1, Part 1, after entry for Amoxicillin in the form Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL *[Brand: Amoxil; Maximum Quantity: 1; Number of Repeats: 1]*

insert:

Amoxicillin	Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL	Oral	Amoxycillin Sandoz	SZ	PDP		1	0	1
Amoxicillin	Powder for oral suspension 125 mg (as trihydrate) per	Oral	Amoxycillin Sandoz	SZ	MP NP		1	1	1

	5 mL, 100 mL											

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

insert:

Amoxicillin with clavulanic acid	Powder for oral suspension containing 125 mg amoxicillin (as trihydrate) with 31.25 mg clavulanic acid (as potassium clavulanate) per 5 mL, 100 mL (S19A)	Oral	CLAVULIN-125F (GlaxoSmithKline, Canada)	DZ	PDP	C5833 C5894	P5833 P5894	1	0	1	
Amoxicillin with clavulanic acid	Powder for oral suspension containing 125 mg amoxicillin (as trihydrate) with 31.25 mg clavulanic acid (as potassium clavulanate) per 5 mL, 100 mL (S19A)	Oral	CLAVULIN-125F (GlaxoSmithKline, Canada)	DZ	MP NP	C5832 C5893	P5832 P5893	1	1	1	

[24] Schedule 1, Part 1, after entry for Aprepitant *[Brand: Aprepitant APOTEX]*

insert:

Aprepitant	Capsule 165 mg	Oral	Aprepitant APOTEX	TX	MP	C4216 C4223 C6383 C6464	1	5	1	C(100)

[25] Schedule 1, Part 1, after entry for Aprepitant *[Brand: APREPITANT SCP]*

insert:

Aprepitant	Capsule 165 mg	Oral	APREPITANT SCP	XC	MP	C4216 C4223 C6383 C6464	1	5	1	C(100)

[26] Schedule 1, Part 1, entry for Aripiprazole in the form Tablet 10 mg

omit:

Aripiprazole	Tablet 10 mg	Oral	Tevaripiprazole	TB	MP NP	C4246	30	5	30	

[27] Schedule 1, Part 1, entry for Aripiprazole in the form Tablet 15 mg

omit:

Aripiprazole	Tablet 15 mg	Oral	Tevaripiprazole	TB	MP NP	C4246		30	5	30

[28] Schedule 1, Part 1, entry for Aripiprazole in the form Tablet 20 mg

omit:

Aripiprazole	Tablet 20 mg	Oral	Tevaripiprazole	TB	MP NP	C4246		30	5	30

[29] Schedule 1, Part 1, entry for Aripiprazole in the form Tablet 30 mg

omit:

Aripiprazole	Tablet 30 mg	Oral	Tevaripiprazole	TB	MP NP	C4246		30	5	30

[30] Schedule 1, Part 1, entry for Atorvastatin in the form Tablet 80 mg (as calcium)

omit:

Atorvastatin	Tablet 80 mg (as calcium)	Oral	Atorvastatin GH	GQ	MP NP			30	5	30
Atorvastatin	Tablet 80 mg (as calcium)	Oral	Atorvastatin GH	GQ	MP NP		P14238	60	5	30

[31] Schedule 1, Part 1, after entry for Auranofin in the form Tablet 3 mg

insert:

Avacopan	Capsule 10 mg	Oral	Tavneos	CS	MP	C15894		180	5	180

[32] Schedule 1, Part 1, entry for Azithromycin in the form Tablet 500 mg (as dihydrate)

omit:

Azithromycin	Tablet 500 mg (as dihydrate)	Oral	Azithromycin Mylan	AF	MP NP	C5718 C5772	P5718 P5772	2	0	2

Azithromycin	Tablet 500 mg (as dihydrate)	Oral	Azithromycin Mylan	AF	MP NP	C5637	P5637	2	2	2	

[33] Schedule 1, Part 1, entry for Beclometasone with formoterol and glycopyrronium in the form Pressurised inhalation containing beclometasone dipropionate 100 micrograms with formoterol fumarate dihydrate 6 micrograms and glycopyrronium 10 micrograms (as bromide) per dose, 120 doses *[Maximum Quantity: 1; Number of Repeats: 5]*

(a) *insert in numerical order in the column headed "Circumstances":* **C12603**

(b) *insert in numerical order in the column headed "Purposes":* **P12603**

[34] Schedule 1, Part 1, entry for Bendamustine in the form Powder for injection containing bendamustine hydrochloride 25 mg

omit:

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

[35] Schedule 1, Part 1, entry for Bendamustine in the form Powder for injection containing bendamustine hydrochloride 100 mg

omit:

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

[36] Schedule 1, Part 1, after entry for Bevacizumab in the form Solution for I.V. infusion 100 mg in 4 mL *[Brand: Mvasi]*

insert:

Bevacizumab	Solution for I.V. infusion 100 mg in 4 mL	Injection	Vegzelma	EW	MP		See Note 3	See Note 3	1	D(100)

[37] Schedule 1, Part 1, after entry for Bevacizumab in the form Solution for I.V. infusion 400 mg in 16 mL *[Brand: Mvasi]*

insert:

Bevacizumab	Solution for I.V. infusion 400 mg in 16 mL	Injection	Vegzelma	EW	MP		See Note 3	See Note 3	1	D(100)

[38] Schedule 1, Part 1, entries for Bimekizumab

substitute:

Bimekizumab	Injection 160 mg in 1 mL single use pre-filled pen	Injection	Bimzelx	UC	MP	C9064 C14217 C15149 C15150 C15857 C15874 C15891 C15916 C15938 C15939 C15940 C15950	P9064 P14217 P15149 P15150 P15857 P15874 P15891 P15916 P15938 P15939 P15940 P15950	2	1	2
Bimekizumab	Injection 160 mg in 1 mL single use pre-filled pen	Injection	Bimzelx	UC	MP	C10434 C10807 C14375 C14376 C15140 C15859 C15890 C15902 C15903 C15917 C15937 C15949	P10434 P10807 P14375 P14376 P15140 P15859 P15890 P15902 P15903 P15917 P15937 P15949	2	2	2
Bimekizumab	Injection 160 mg in 1 mL single use pre-filled pen	Injection	Bimzelx	UC	MP	C14374 C14396 C14425 C14437 C14448 C14449 C14460	P14374 P14396 P14425 P14437 P14448 P14449 P14460	2	4	2

[39] Schedule 1, Part 1, entries for Bisacodyl in the form Suppositories 10 mg, 10

substitute:

Bisacodyl	Suppositories 10 mg, 10	Rectal	Dulcolax	VZ	MP NP	C5640 C5775 C5819 C5823 C5851 C5866 C5879	P5640 P5775 P5819 P5823 P5851 P5866 P5879	3	5	1
Bisacodyl	Suppositories 10 mg, 10	Rectal	Dulcolax	VZ	MP NP	C15535 C15585 C15586 C15587 C15708 C15726 C15727	P15535 P15585 P15586 P15587 P15708 P15726 P15727	6	5	1
Bisacodyl	Suppositories 10 mg, 10	Rectal	Petrus Bisacodyl Suppositories	PP	MP NP	C5640 C5775 C5819 C5823 C5851 C5866 C5879	P5640 P5775 P5819 P5823 P5851 P5866 P5879	3	5	1
Bisacodyl	Suppositories 10 mg, 10	Rectal	Petrus Bisacodyl Suppositories	PP	MP NP	C15535 C15585 C15586 C15587	P15535 P15585 P15586 P15587	6	5	1

							C15708 C15726 C15727	P15708 P15726 P15727			

[40] Schedule 1, Part 1, 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

omit:

Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	BiResp Spiromax	TB	MP NP	C10464	P10464	1	2	1
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	BiResp Spiromax	TB	MP NP	C7970	P7970	1	5	1
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	BiResp Spiromax	TB	MP	C10538	P10538	1	5	1
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	BiResp Spiromax	TB	MP NP	C15680	P15680	2	5	1
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with	Inhalation by mouth	BiResp Spiromax	TB	MP	C15577	P15577	2	5	1

	formoterol fumarate dihydrate 6 micrograms per dose, 120 doses

[41] 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

omit:

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	Inhalation by mouth	BiResp Spiromax	TB	MP NP	C7979 C10121	P7979 P10121	2	5	2
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	Inhalation by mouth	BiResp Spiromax	TB	MP NP	C15548 C15617	P15548 P15617	4	5	2

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

omit from the column headed "Responsible Person": **EU** *substitute:* **JA**

[43] Schedule 1, Part 1, after entry for Carbamazepine in the form Oral suspension 100 mg per 5 mL, 300 mL *[Maximum Quantity: 2; Number of Repeats: 5]*

insert:

Carbamazepine	Tablet 100 mg	Oral	AVLOIRE	VQ	PDP			200	0	100
Carbamazepine	Tablet 100 mg	Oral	AVLOIRE	VQ	MP NP			200	2	100
Carbamazepine	Tablet 100 mg	Oral	AVLOIRE	VQ	MP NP		P14238	400	2	100

[44] Schedule 1, Part 1, after entry for Carbamazepine in the form Tablet 100 mg *[Brand: Tegretol 100; Maximum Quantity: 400; Number of Repeats: 2]*

insert:

Carbamazepine	Tablet 200 mg	Oral	AVLOIRE	VQ	PDP		200	0	100
Carbamazepine	Tablet 200 mg	Oral	AVLOIRE	VQ	MP NP		200	2	100
Carbamazepine	Tablet 200 mg	Oral	AVLOIRE	VQ	MP NP	P14238	400	2	100

[45] Schedule 1, Part 1, entry for Carmellose in the form Eye drops containing carmellose sodium 5 mg per mL, 15 mL

omit:

Carmellose	Eye drops containing carmellose sodium 5 mg per mL, 15 mL	Application to the eye	Refresh Tears Plus	VE	AO NP C6120	P6120	1	5	1

[46] Schedule 1, Part 1, entry for Carmellose in the form Eye drops containing carmellose sodium 5 mg per mL, 15 mL *[Authorised Prescriber: MP; Maximum Quantity: 1; Number of Repeats: 5]*

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

[47] Schedule 1, Part 1, entry for Carmellose in the form Eye drops containing carmellose sodium 10 mg per mL, 15 mL

omit:

Carmellose	Eye drops containing carmellose sodium 10 mg per mL, 15 mL	Application to the eye	Refresh Liquigel	VE	AO NP C6120	P6120	1	5	1

[48] Schedule 1, Part 1, entry for Carmellose in the form Eye drops containing carmellose sodium 10 mg per mL, 15 mL *[Authorised Prescriber: MP; Maximum Quantity: 1; Number of Repeats: 5]*

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

[49] Schedule 1, Part 1, after entry for Celecoxib in the form Capsule 100 mg *[Brand: APX-Celecoxib]*

insert:

Celecoxib	Capsule 100 mg	Oral	Blooms Celecoxib	BG	MP NP	C4907 C4962	60	3	60

[50] Schedule 1, Part 1, after entry for Celecoxib in the form Capsule 200 mg *[Brand: APX-Celecoxib]*

insert:

Celecoxib	Capsule 200 mg	Oral	Blooms Celecoxib	BG	MP NP	C4907 C4962	30	3	30

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

omit:

Ciprofloxacin	Tablet 500 mg (as hydrochloride)	Oral	Cifran	RA	MP NP	C5614 C5615 C5687 C5688 C5689 C5722 C5780	14	0	14

[52] Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg

omit:

Cyproterone	Tablet containing cyproterone acetate 50 mg	Oral	Pharmacor Cyproterone 50	CR	MP	P5532	20 CN5532	5 CN5532	20
Cyproterone	Tablet containing cyproterone acetate 50 mg	Oral	Pharmacor Cyproterone 50	CR	MP	P14868	40 CN14868	5 CN14868	20
Cyproterone	Tablet containing cyproterone acetate 50 mg	Oral	Pharmacor Cyproterone 50	CR	MP		100	5	50
Cyproterone	Tablet containing cyproterone acetate 50 mg	Oral	Pharmacor Cyproterone 50	CR	MP	P14238	200	5	50

[53] Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 100 m

omit:

Cyproterone	Tablet containing cyproterone acetate 100 mg	Oral	Pharmacor Cyproterone 100	CR	MP		50	5	50

Cyproterone	Tablet containing cyproterone acetate 100 mg	Oral	Pharmacor Cyproterone 100	CR	MP	P14238	100	5	50	

[54] Schedule 1, Part 1, entry for Dabigatran etexilate in the form Capsule 75 mg (as mesilate)

omit:

Dabigatran etexilate	Capsule 75 mg (as mesilate)	Oral	PHARMACOR DABIGATRAN	CR	MP NP	C4402	60	0	60	

[55] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 20 mg

omit:

Dasatinib	Tablet 20 mg	Oral	TE-DASATINIB	AF	MP	C9367 C9468 C9469 C9549	P9367 P9468 P9469 P9549	60	2	60
Dasatinib	Tablet 20 mg	Oral	TE-DASATINIB	AF	MP	C12522 C12524 C12530 C12561 C12565 C12570	P12522 P12524 P12530 P12561 P12565 P12570	60	5	60

[56] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 50 mg

omit:

Dasatinib	Tablet 50 mg	Oral	TE-DASATINIB	AF	MP	C9367 C9468 C9469 C9549	P9367 P9468 P9469 P9549	60	2	60
Dasatinib	Tablet 50 mg	Oral	TE-DASATINIB	AF	MP	C12522 C12524 C12530 C12561 C12565 C12570	P12522 P12524 P12530 P12561 P12565 P12570	60	5	60

[57] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 70 mg

omit:

Dasatinib	Tablet 70 mg	Oral	TE-DASATINIB	AF	MP	C9367 C9468 C9469 C9549	P9367 P9468 P9469 P9549	60	2	60
Dasatinib	Tablet 70 mg	Oral	TE-DASATINIB	AF	MP	C12522 C12524 C12530 C12561 C12565 C12570	P12522 P12524 P12530 P12561 P12565 P12570	60	5	60

[58] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 100 mg

omit:

Dasatinib	Tablet 100 mg	Oral	TE-DASATINIB	AF	MP	C9367 C9468 C9469 C9549	P9367 P9468 P9469 P9549	30	2	30
Dasatinib	Tablet 100 mg	Oral	TE-DASATINIB	AF	MP	C12522 C12524 C12530 C12561 C12565 C12570	P12522 P12524 P12530 P12561 P12565 P12570	30	5	30

[59] Schedule 1, Part 1, entry for Desvenlafaxine in the form Tablet (modified release) 50 mg *[Brand: Desvenlafaxine Sandoz; Maximum Quantity: 28; Number of Repeats: 5]*

insert in the column headed "Purposes": **P5650**

[60] Schedule 1, Part 1, entry for Dexamethasone with framycetin and gramicidin in the form Ear drops containing dexamethasone 500 micrograms (as sodium metasulfobenzoate), framycetin sulfate 5 mg and gramicidin 50 micrograms per mL, 8 mL *[Brand: Otodex]*

omit from the column headed "Responsible Person": **AV** *substitute:* **FQ**

[61] Schedule 1, Part 1, entry for Dexamethasone with framycetin and gramicidin in the form Ear drops containing dexamethasone 500 micrograms (as sodium metasulfobenzoate), framycetin sulfate 5 mg and gramicidin 50 micrograms per mL, 8 mL *[Brand: Sofradex]*

omit from the column headed "Responsible Person": **SW** *substitute:* **PB**

[62] Schedule 1, Part 1, entry for Dicloxacillin in the form Capsule 500 mg (as sodium)

omit:

Dicloxacillin	Capsule 500 mg (as sodium)	Oral	Dicloxacillin Mylan 500	AL	PDP	C5268	P5268	24	0	24
Dicloxacillin	Capsule 500 mg (as sodium)	Oral	Dicloxacillin Mylan 500	AL	MP NP MW	C5415	P5415	24	0	24
Dicloxacillin	Capsule 500 mg (as sodium)	Oral	Dicloxacillin Mylan 500	AL	MP	C6188	P6188	48	1	24

[63] Schedule 1, Part 1, entry for Donepezil in the form Tablet containing donepezil hydrochloride 5 mg

omit:

Donepezil	Tablet containing donepezil hydrochloride 5 mg	Oral	NOUMED DONEPEZIL	VO	MP NP	C13938	28	5	28	
Donepezil	Tablet containing donepezil hydrochloride 5 mg	Oral	NOUMED DONEPEZIL	VO	MP	C13940 C13941	28	5	28	

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

omit:

Donepezil	Tablet containing donepezil hydrochloride 10 mg	Oral	NOUMED DONEPEZIL	VO	MP NP	C13938	28	5	28	
Donepezil	Tablet containing donepezil hydrochloride 10 mg	Oral	NOUMED DONEPEZIL	VO	MP	C13940 C13941	28	5	28	

[65] Schedule 1, Part 1, entry for Duloxetine in the form Capsule 30 mg (as hydrochloride) *[Brand: Tixol]*

omit from the column headed "Brand": **Tixol** *substitute:* **Tixol 30**

[66] Schedule 1, Part 1, entry for Duloxetine in the form Capsule 60 mg (as hydrochloride) *[Brand: Tixol]*

omit from the column headed "Brand": **Tixol** *substitute:* **Tixol 60**

[67] Schedule 1, Part 1, entries for Dupilumab

substitute:

Dupilumab	Injection 200 mg in 1.14 mL single dose pre-filled syringe	Injection	Dupixent	SW	MP	C11374 C11377 C12497 C12507	P11374 P11377 P12497 P12507	2	5	2	
Dupilumab	Injection 200 mg in 1.14 mL single dose pre-filled syringe	Injection	Dupixent	SW	MP	C15348 C15886 C15924	See Note 3	See Note 3	See Note 3	2	C(100)
Dupilumab	Injection 300 mg in 2 mL single dose pre-filled syringe	Injection	Dupixent	SW	MP	C11374 C11377 C12497 C1250a7	P11374 P11377 P12497 P12507	2	5	2	
Dupilumab	Injection 300 mg in 2 mL single dose pre-filled syringe	Injection	Dupixent	SW	MP	C15348 C15424 C15425	See Note 3	See Note 3	See Note 3	2	C(100)

[68] Schedule 1, Part 1, after entry for Dutasteride with tamsulosin *[Brand: Duodart 500ug/400ug; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Dutasteride with tamsulosin	Capsule containing dutasteride 500 micrograms with tamsulosin hydrochloride 400 micrograms	Oral	DUTATAM 500/400	TN	MP NP	C6189	P6189	30	5	30
Dutasteride with tamsulosin	Capsule containing dutasteride 500 micrograms with tamsulosin hydrochloride 400 micrograms	Oral	DUTATAM 500/400	TN	MP NP	C15004	P15004	60	5	30

[69] Schedule 1, Part 1, entry for Enalapril in the form Tablet containing enalapril maleate 20 mg

omit:

Enalapril	Tablet containing enalapril maleate 20 mg	Oral	Enalapril generichealth	GQ	MP NP			30	5	30
Enalapril	Tablet containing enalapril maleate 20 mg	Oral	Enalapril generichealth	GQ	MP NP		P14238	60	5	30

[70] Schedule 1, Part 1, entry for Entecavir in the form Tablet 0.5 mg (as monohydrate)

omit:

Entecavir	Tablet 0.5 mg (as monohydrate)	Oral	Entecavir Mylan	AF	MP NP	C4993 C5036		60	5	30	D(100)

[71] Schedule 1, Part 1, entry for Esomeprazole in the form Capsule (enteric) 20 mg (as magnesium) *[Maximum Quantity: 120; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[72] **Schedule 1, Part 1, entry for Esomeprazole in the form Capsule (enteric) 40 mg (as magnesium) *[Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15705** *substitute:* **C15936**

(b) *omit from the column headed "Purposes":* **P15705** *substitute:* **P15936**

[73] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate) *[Brand: APO-Esomeprazole; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[74] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate) *[Brand: Esomeprazole GH; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[75] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate) *[Brand: Esomeprazole GxP; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[76] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate) *[Brand: Esomeprazole Mylan; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[77] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate) *[Brand: Esomeprazole RBX; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[78] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate)** ***[Brand: Esomeprazole Viatris; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[79] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate)** ***[Brand: ESOMEPRAZOLE-WGR; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[80] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate)** ***[Brand: Esopreze; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[81] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate)** ***[Brand: Nexazole; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[82] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate)** ***[Brand: Nexium; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[83] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate)** ***[Brand: Nexole; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[84] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate)**

omit:

Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate)	Oral	NOUMED ESOMEPRAZOLE	VO	MP NP	C8774 C8775	P8774 P8775	30	1	30
Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate)	Oral	NOUMED ESOMEPRAZOLE	VO	MP NP	C8776 C8780 C8827	P8776 P8780 P8827	30	5	30
Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate)	Oral	NOUMED ESOMEPRAZOLE	VO	MP	C11310	P11310	60	5	30
Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate)	Oral	NOUMED ESOMEPRAZOLE	VO	MP NP	C15530 C15658 C15682	P15530 P15658 P15682	60	5	30
Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate)	Oral	NOUMED ESOMEPRAZOLE	VO	MP	C15531	P15531	120	5	30

[85] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate)** ***[Brand: APO-Esomeprazole; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15705** *substitute:* **C15936**

(b) *omit from the column headed "Purposes":* **P15705** *substitute:* **P15936**

[86] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate)** ***[Brand: Esomeprazole GH; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15705** *substitute:* **C15936**

(b) *omit from the column headed "Purposes":* **P15705** *substitute:* **P15936**

[87] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate)** ***[Brand: Esomeprazole GxP; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15705** *substitute:* **C15936**

(b) *omit from the column headed "Purposes":* **P15705** *substitute:* **P15936**

[88] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate)** ***[Brand: Esomeprazole Mylan; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15705** *substitute:* **C15936**

(b) *omit from the column headed "Purposes":* **P15705** *substitute:* **P15936**

[89] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate) *[Brand: Esomeprazole RBX; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15705** *substitute:* **C15936**

(b) *omit from the column headed "Purposes":* **P15705** *substitute:* **P15936**

[90] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate) *[Brand: Esomeprazole Viatris; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15705** *substitute:* **C15936**

(b) *omit from the column headed "Purposes":* **P15705** *substitute:* **P15936**

[91] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate) *[Brand: ESOMEPRAZOLE-WGR; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15705** *substitute:* **C15936**

(b) *omit from the column headed "Purposes":* **P15705** *substitute:* **P15936**

[92] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate) *[Brand: Esopreze; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15705** *substitute:* **C15936**

(b) *omit from the column headed "Purposes":* **P15705** *substitute:* **P15936**

[93] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate) *[Brand: Nexazole; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15705** *substitute:* **C15936**

(b) *omit from the column headed "Purposes":* **P15705** *substitute:* **P15936**

[94] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate) *[Brand: Nexium; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15705** *substitute:* **C15936**

(b) *omit from the column headed "Purposes":* **P15705** *substitute:* **P15936**

[95] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate) *[Brand: Nexole; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15705** *substitute:* **C15936**

(b) *omit from the column headed "Purposes":* **P15705** *substitute:* **P15936**

[96] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate)**

omit:

Esomeprazole	Tablet (enteric coated) 40 mg (as magnesium trihydrate)	Oral	NOUMED ESOMEPRAZOLE	VO	MP NP	C8902	P8902	30	1	30
Esomeprazole	Tablet (enteric coated) 40 mg (as magnesium trihydrate)	Oral	NOUMED ESOMEPRAZOLE	VO	MP NP	C8777 C8778	P8777 P8778	30	5	30
Esomeprazole	Tablet (enteric coated) 40 mg (as magnesium trihydrate)	Oral	NOUMED ESOMEPRAZOLE	VO	MP	C11370	P11370	60	5	30
Esomeprazole	Tablet (enteric coated) 40 mg (as magnesium trihydrate)	Oral	NOUMED ESOMEPRAZOLE	VO	MP NP	C15655 C15704	P15655 P15704	60	5	30
Esomeprazole	Tablet (enteric coated) 40 mg (as magnesium trihydrate)	Oral	NOUMED ESOMEPRAZOLE	VO	MP	C15705	P15705	120	5	30

[97] **Schedule 1, Part 1, after entry for Etoposide in the form Solution for I.V. infusion 100 mg in 5 mL**

insert:

Etrasimod	Tablet 2 mg	Oral	Velsipity	PF	MP	C15851 C15887 C15946 C15947	P15851 P15887 P15946 P15947	28	3	28
Etrasimod	Tablet 2 mg	Oral	Velsipity	PF	MP	C15853 C15888 C15926	P15853 P15888 P15926	28	5	28

[98] **Schedule 1, Part 1, after entry for Fluconazole in the form Capsule 100 mg *[Brand: Ozole]***

insert:

Fluconazole	Capsule 200 mg	Oral	APO-Fluconazole	TX	MP NP	C5978 C5989 C6002 C6023 C6030 C7898	28	5	28

[99] Schedule 1, Part 1, entry for Fluoxetine

omit:

Fluoxetine	Capsule 10 mg (Medreich) (S19A)	Oral	Fluoxetine Capsules 10 mg (Medreich, UK)	LM	MP NP	C14828 C14832	30	5	30

[100] Schedule 1, Part 1, entry for Fluticasone propionate in the form Pressurised inhalation containing fluticasone propionate 50 micrograms per dose, 120 doses (CFC-free formulation) *[Brand: Axotide Junior; Maximum Quantity: 2; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C14238** *substitute:* **C15854**

(b) *omit from the column headed "Purposes":* **P14238** *substitute:* **P15854**

[101] Schedule 1, Part 1, entry for Fluticasone propionate in the form Pressurised inhalation containing fluticasone propionate 50 micrograms per dose, 120 doses (CFC-free formulation) *[Brand: Flixotide Junior; Maximum Quantity: 2; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C14238** *substitute:* **C15854**

(b) *omit from the column headed "Purposes":* **P14238** *substitute:* **P15854**

[102] Schedule 1, Part 1, entries for Framycetin

substitute:

Framycetin	Eye or ear drops containing framycetin sulfate 5 mg per mL, 8 mL	Application to the eye ear	Soframycin	PB	MP NP MW AO		1	2	1

[103] Schedule 1, Part 1, entry for Gabapentin in the form Capsule 300 mg

omit:

Gabapentin	Capsule 300 mg	Oral	Gabapentin generichealth	HQ	MP NP	C4928	100	5	100

[104] Schedule 1, Part 1, entry for Gabapentin in the form Capsule 400 mg

omit:

Gabapentin	Capsule 400 mg	Oral	Gabapentin genericehealth	HQ	MP NP	C4928		100	5	100

[105] Schedule 1, Part 1, entries for Ibrutinib

substitute:

Ibrutinib	Capsule 140 mg	Oral	Imbruvica	JC	MP	C15864	P15864	90	2	90
Ibrutinib	Capsule 140 mg	Oral	Imbruvica	JC	MP	C15863	P15863	90	4	90
Ibrutinib	Capsule 140 mg	Oral	Imbruvica	JC	MP	C14788 C15861 C15892	P14788 P15861 P15892	90	5	90
Ibrutinib	Capsule 140 mg	Oral	Imbruvica	JC	MP	C12495 C12500	P12495 P12500	120	5	120
Ibrutinib	Tablet 280 mg	Oral	Imbruvica	JC	MP	C15864	P15864	30	2	30
Ibrutinib	Tablet 280 mg	Oral	Imbruvica	JC	MP	C15863	P15863	30	4	30
Ibrutinib	Tablet 280 mg	Oral	Imbruvica	JC	MP	C12495 C12500 C14788 C15861 C15892	P12495 P12500 P14788 P15861 P15892	30	5	30
Ibrutinib	Tablet 420 mg	Oral	Imbruvica	JC	MP	C15864	P15864	30	2	30
Ibrutinib	Tablet 420 mg	Oral	Imbruvica	JC	MP	C15863	P15863	30	4	30
Ibrutinib	Tablet 420 mg	Oral	Imbruvica	JC	MP	C12495 C12500 C14788 C15861 C15892	P12495 P12500 P14788 P15861 P15892	30	5	30
Ibrutinib	Tablet 560 mg	Oral	Imbruvica	JC	MP	C12495 C12500		30	5	30

[106] Schedule 1, Part 1, after entry for Icatibant in the form Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe *[Brand: Icatibant Lupin]*

insert:

Icosapent ethyl	Capsule 998 mg	Oral	Vazkepa	CS	MP	C15889 C15927	120	5	120

[107] Schedule 1, Part 1, after entry for Imatinib in the form Tablet 100 mg (as mesilate) *[Brand: Glivec; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Imatinib	Tablet 100 mg (as mesilate)	Oral	Imanib	AF	MP	C9203 C9207 C12525 C12527 C12542 C12543	P9203 P9207 P12525 P12527 P12542 P12543	60	2	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	Imanib	AF	MP	C9204 C9206 C9209 C9240 C9243 C9274 C9276 C9296 C12536 C12541	P9204 P9206 P9209 P9240 P9243 P9274 P9276 P9296 P12536 P12541	60	5	60

[108] Schedule 1, Part 1, after entry for Imatinib in the form Tablet 400 mg (as mesilate) *[Brand: Glivec; Maximum Quantity: 30; Number of Repeats: 5]*

insert:

Imatinib	Tablet 400 mg (as mesilate)	Oral	Imanib	AF	MP	C9203 C9207 C12525 C12527 C12542 C12543	P9203 P9207 P12525 P12527 P12542 P12543	30	2	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	Imanib	AF	MP	C9204 C9206 C9209 C9240 C9243 C9274 C9276 C9296 C12536 C12541	P9204 P9206 P9209 P9240 P9243 P9274 P9276 P9296 P12536 P12541	30	5	30

[109] Schedule 1, Part 1, after entry for Lamivudine in the form Tablet 150 mg *[Brand: Lamivudine Alphapharm]*

insert:

Lamivudine	Tablet 150 mg	Oral	Lamivudine Viatris	AL	MP NP	C4454 C4512		120	5	60	D(100)

[110] Schedule 1, Part 1, entry for Lansoprazole in the form Capsule 30 mg *[Brand: APO-Lansoprazole; Maximum Quantity: 112; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[111] **Schedule 1, Part 1, entry for Lansoprazole in the form Capsule 30 mg *[Brand: Lanzopran; Maximum Quantity: 112; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[112] **Schedule 1, Part 1, entry for Lansoprazole in the form Capsule 30 mg *[Brand: NOUMED LANSOPRAZOLE; Maximum Quantity: 112; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[113] **Schedule 1, Part 1, entry for Lansoprazole in the form Capsule 30 mg *[Brand: Zopral; Maximum Quantity: 112; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[114] **Schedule 1, Part 1, entry for Lansoprazole in the form Tablet 30 mg (orally disintegrating) *[Brand: APO-Lansoprazole ODT; Maximum Quantity: 112; Number of* Repeats*: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[115] **Schedule 1, Part 1, entry for Lansoprazole in the form Tablet 30 mg (orally disintegrating) *[Brand: Lansoprazole ODT GH; Maximum Quantity: 112; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[116] **Schedule 1, Part 1, entry for Lansoprazole in the form Tablet 30 mg (orally disintegrating) *[Brand: Zopral ODT; Maximum Quantity: 112; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[117] **Schedule 1, Part 1, entry for Lansoprazole in the form Tablet 30 mg (orally disintegrating) *[Brand: Zoton FasTabs; Maximum Quantity: 112; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[118] Schedule 1, Part 1, after entry for Lenalidomide in the form Capsule 15 mg *[Brand: Revlimid; Pack Quantity:28]*

insert:

Lenalidomide	Capsule 20 mg	Oral	Lenalide	JU	MP	See Note 3	See Note 3	See Note 3	See Note 3	14		D(100)
Lenalidomide	Capsule 20 mg	Oral	Lenalide	JU	MP	See Note 3	See Note 3	See Note 3	See Note 3	21		D(100)

[119] Schedule 1, Part 1, after entry for Lidocaine in the form Infusion containing lidocaine hydrochloride 500 mg in 5 mL

insert:

Lidocaine	Injection containing lidocaine hydrochloride monohydrate 50 mg in 5 mL	Injection	LIGNOCAINE INJECTION (BRIDGEWEST)	WZ	See Note 4	See Note 4	See Note 4	See Note 4	See Note 4	5	5	PB(MP) PB(NP)

[120] Schedule 1, Part 1, entry for Lidocaine in the form Injection containing lidocaine hydrochloride monohydrate 50 mg in 5 mL

omit:

Lidocaine	Injection containing lidocaine hydrochloride monohydrate 50 mg in 5 mL	Injection	Lignocaine Injection (Pfizer)	WZ	See Note 4	See Note 4	See Note 4	See Note 4	See Note 4	5	5	PB(MP) PB(NP)

[121] Schedule 1, Part 1, entry for Lisinopril in the form Tablet 20 mg

omit:

Lisinopril	Tablet 20 mg	Oral	Lisinopril generichealth	GQ	MP NP			30	5	30		
Lisinopril	Tablet 20 mg	Oral	Lisinopril generichealth	GQ	MP NP		P14238	60	5	30		

[122] Schedule 1, Part 1, entry for Meloxicam in the form Tablet 7.5 mg

omit:

Meloxicam	Tablet 7.5 mg	Oral	Pharmacor Meloxicam 7.5	CR	MP NP	C4907 C4962		30	3	30

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

omit:

Meloxicam	Tablet 15 mg	Oral	Pharmacor Meloxicam 15	CR	MP NP	C4907 C4962		30	3	30

[124] Schedule 1, Part 1, after entry for Metformin in the form Tablet (extended release) containing metformin hydrochloride 500 mg *[Brand: Diabex XR 500; Maximum Quantity: 240; Number of Repeats: 5]*

insert:

Metformin	Tablet (extended release) containing metformin hydrochloride 500 mg	Oral	Diaformin Alphapharm XR	MQ	MP NP			120	5	120
Metformin	Tablet (extended release) containing metformin hydrochloride 500 mg	Oral	Diaformin Alphapharm XR	MQ	MP NP		P14238	240	5	120

[125] Schedule 1, Part 1, after entry for Metformin in the form Tablet (extended release) containing metformin hydrochloride 1 g *[Brand: Diabex XR 1000; Maximum Quantity: 120; Number of Repeats: 5]*

insert:

Metformin	Tablet (extended release) containing metformin hydrochloride 1 g	Oral	Diaformin Alphapharm XR	MQ	MP NP			60	5	60
Metformin	Tablet (extended release) containing metformin hydrochloride 1 g	Oral	Diaformin Alphapharm XR	MQ	MP NP		P14238	120	5	60

[126] Schedule 1, Part 1, entries for Metronidazole

substitute:

Metronidazole	Oral suspension containing metronidazole benzoate 320 mg per 5 mL, 100 mL	Oral	Flagyl S	SW	MP NP PDP			1	0	1
Metronidazole	Suppositories 500 mg, 10	Rectal	Flagyl	SW	MP NP PDP			1	0	1
Metronidazole	Tablet 200 mg	Oral	Metrogyl 200	AF	PDP			21	0	21
Metronidazole	Tablet 200 mg	Oral	Metrogyl 200	AF	MP NP			21	1	21
Metronidazole	Tablet 200 mg	Oral	METRONIDAMED	DZ	PDP			21	0	21
Metronidazole	Tablet 200 mg	Oral	METRONIDAMED	DZ	MP NP			21	1	21
Metronidazole	Tablet 400 mg	Oral	Flagyl	SW	PDP	C5701	P5701	21	0	21
Metronidazole	Tablet 400 mg	Oral	Flagyl	SW	MP NP	C5702	P5702	21	1	21
Metronidazole	Tablet 400 mg	Oral	Metrogyl 400	AF	PDP	C5701	P5701	21	0	21
Metronidazole	Tablet 400 mg	Oral	Metrogyl 400	AF	MP NP	C5702	P5702	21	1	21
Metronidazole	Tablet 400 mg	Oral	METRONIDAMED	DZ	PDP	C5701	P5701	21	0	21
Metronidazole	Tablet 400 mg	Oral	METRONIDAMED	DZ	MP NP	C5702	P5702	21	1	21

[127] Schedule 1, Part 1, after entry for Mometasone in the form Ointment containing mometasone furoate 1 mg per g, 15 g *[Brand: Zatamil; Maximum Quantity: 10; Number of Repeats: 5]*

insert:

Montelukast	Tablet, chewable, 4 mg (as sodium)	Oral	APX-MONTELUKAST	TX	MP NP	C6666	P6666	28	5	28
Montelukast	Tablet, chewable, 4 mg (as sodium)	Oral	APX-MONTELUKAST	TX	MP NP	C15642	P15642	56	5	28

[128] Schedule 1, Part 1, after entry for Montelukast in the form Tablet, chewable, 4 mg (as sodium) *[Brand: Montelukast Viatris; Maximum Quantity: 56; Number of Repeats: 5]*

insert:

Montelukast	Tablet, chewable, 4 mg (as sodium)	Oral	MONTELUKAST-WGR	WG	MP NP	C6666	P6666	28	5	28
Montelukast	Tablet, chewable, 4 mg (as sodium)	Oral	MONTELUKAST-WGR	WG	MP NP	C15642	P15642	56	5	28
Montelukast	Tablet, chewable, 5 mg (as sodium)	Oral	APX-MONTELUKAST	TX	MP NP	C6674 C7781	P6674 P7781	28	5	28
Montelukast	Tablet, chewable, 5 mg (as sodium)	Oral	APX-MONTELUKAST	TX	MP NP	C15643 C15644	P15643 P15644	56	5	28

[129] Schedule 1, Part 1, after entry for Montelukast in the form Tablet, chewable, 5 mg (as sodium) *[Brand: Montelukast Viatris; Maximum Quantity: 56; Number of Repeats: 5]*

insert:

Montelukast	Tablet, chewable, 5 mg (as sodium)	Oral	MONTELUKAST-WGR	WG	MP NP	C6674 C7781	P6674 P7781	28	5	28
Montelukast	Tablet, chewable, 5 mg (as sodium)	Oral	MONTELUKAST-WGR	WG	MP NP	C15643 C15644	P15643 P15644	56	5	28

[130] Schedule 1, Part 1, after entry for Olanzapine in the form Tablet 2.5 mg *[Brand: Zyprexa]*

insert:

Olanzapine	Tablet 5 mg	Oral	APO-OLANZAPINE	TX	MP NP	C5856 C5869		28	5	28

[131] Schedule 1, Part 1, after entry for Olmesartan with amlodipine in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) *[Brand: Sevikar 40/10; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Olmesartan with amlodipine	Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate)	Oral	APO-OLMESARTAN/AMLODIPINE 40/5	TY	MP NP	C4373	P4373	30	5	30

Olmesartan with amlodipine	Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate)	Oral	APO-OLMESARTAN/AMLODIPINE 40/5	TY	MP NP	C14839	P14839	60	5	30

[132] Schedule 1, Part 1, entry for Omeprazole in the form Capsule 20 mg *[Brand: APO-Omeprazole; Maximum Quantity: 120; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[133] Schedule 1, Part 1, entry for Omeprazole in the form Capsule 20 mg *[Brand: Maxor; Maximum Quantity: 120; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[134] Schedule 1, Part 1, after entry for Omeprazole in the form Capsule 20 mg *[Brand: Maxor; Maximum Quantity: 120; Number of Repeats: 5]*

insert:

Omeprazole	Capsule 20 mg	Oral	OMEPRAZOLE CAPS WGR	WG	MP NP	C8774 C8775	P8774 P8775	30	1	30
Omeprazole	Capsule 20 mg	Oral	OMEPRAZOLE CAPS WGR	WG	MP NP	C8776 C8780 C8866	P8776 P8780 P8866	30	5	30
Omeprazole	Capsule 20 mg	Oral	OMEPRAZOLE CAPS WGR	WG	MP	C11310	P11310	60	5	30
Omeprazole	Capsule 20 mg	Oral	OMEPRAZOLE CAPS WGR	WG	MP NP	C15530 C15658 C15678	P15530 P15658 P15678	60	5	30
Omeprazole	Capsule 20 mg	Oral	OMEPRAZOLE CAPS WGR	WG	MP	C15856	P15856	120	5	30

[135] Schedule 1, Part 1, entry for Omeprazole in the form Capsule 20 mg *[Brand: Omeprazole Sandoz; Maximum Quantity: 120; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[136] **Schedule 1, Part 1, entry for Omeprazole in the form Capsule 20 mg *[Brand: Pemzo; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[137] **Schedule 1, Part 1, entry for Omeprazole in the form Capsule 20 mg *[Brand: Pharmacor Omeprazole 20; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[138] **Schedule 1, Part 1, entry for Omeprazole in the form Capsule 20 mg *[Brand: Probitor; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[139] **Schedule 1, Part 1, entry for Omeprazole in the form Tablet 20 mg *[Brand: APO-Omeprazole; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[140] **Schedule 1, Part 1, entry for Omeprazole in the form Tablet 20 mg *[Brand: Maxor EC Tabs; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[141] **Schedule 1, Part 1, entry for Omeprazole in the form Tablet 20 mg *[Brand: Ozmep; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[142] **Schedule 1, Part 1, entry for Omeprazole in the form Tablet 20 mg (as magnesium) *[Brand: Acimax Tablets; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[143] **Schedule 1, Part 1, entry for Omeprazole in the form Tablet 20 mg (as magnesium)** ***[Brand: Losec Tablets; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[144] **Schedule 1, Part 1, entry for Omeprazole in the form Tablet 20 mg (as magnesium)** ***[Brand: Omepral; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[145] **Schedule 1, Part 1, entry for Omeprazole in the form Tablet 20 mg (as magnesium)** ***[Brand: Omeprazole Sandoz; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[146] **Schedule 1, Part 1, after entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg** ***[Brand: Ondansetron ODT-DRLA; Maximum Quantity: 10; Number of Repeats: 1]***

insert:

Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Ondansetron ODT Viatris	AL	MP NP	C5618	P5618	4	0	V5618	4	
Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Ondansetron ODT Viatris	AL	MP	C5743	P5743	4	0	V5743	4	C(100)
Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Ondansetron ODT Viatris	AL	MP NP	C15193	P15193	10	1		10	

[147] **Schedule 1, Part 1, entry for Oxaliplatin in the form Solution concentrate for I.V. infusion 100 mg in 20 mL**

omit:

Oxaliplatin	Solution concentrate for I.V. infusion 100 mg in 20 mL	Injection	Oxaliplatin SUN	RA	MP			See Note 3	See Note 3		1	D(100)

[148] Schedule 1, Part 1, entries for Oxazepam in the form Tablet 15 mg *[Brand: Alepam 15; Maximum Quantity: 25; Number of Repeats: 0]*

substitute:

Oxazepam	Tablet 15 mg	Oral	Alepam 15	AF	MP NP PDP	25	0	25

[149] Schedule 1, Part 1, entries for Oxazepam in the form Tablet 15 mg *[Brand: Serepax; Maximum Quantity: 25; Number of Repeats: 0]*

substitute:

Oxazepam	Tablet 15 mg	Oral	Serepax	AS	MP NP PDP	25	0	25

[150] Schedule 1, Part 1, entries for Oxazepam in the form Tablet 30 mg *[Brand: Alepam 30; Maximum Quantity: 25; Number of Repeats: 0]*

substitute:

Oxazepam	Tablet 30 mg	Oral	Alepam 30	AF	MP NP PDP	25	0	25

[151] Schedule 1, Part 1, entries for Oxazepam in the form Tablet 30 mg *[Brand: APO-Oxazepam; Maximum Quantity: 25; Number of Repeats: 0]*

substitute:

Oxazepam	Tablet 30 mg	Oral	APO-Oxazepam	TX	MP NP PDP	25	0	25

[152] Schedule 1, Part 1, entries for Oxazepam in the form Tablet 30 mg *[Brand: Murelax; Maximum Quantity: 25; Number of Repeats: 0]*

substitute:

Oxazepam	Tablet 30 mg	Oral	Murelax	RW	MP NP PDP	25	0	25

[153] Schedule 1, Part 1, entries for Oxazepam in the form Tablet 30 mg *[Brand: Serepax; Maximum Quantity: 25; Number of Repeats: 0]*

substitute:

Oxazepam	Tablet 30 mg	Oral	Serepax	AS	MP NP PDP	25	0	25

[154] Schedule 1, Part 1, after entry for Palonosetron in the form Injection 250 micrograms (as hydrochloride) in 5 mL *[Brand: Aloxi]*

insert:

Palonosetron	Injection 250 micrograms (as hydrochloride) in 5 mL	Injection	Aloxi	JZ	MP	C5805	1	0	1	C(100)

[155] Schedule 1, Part 1, after entry for Palonosetron in the form Injection 250 micrograms (as hydrochloride) in 5 mL *[Brand: Palonosetron Dr.Reddy's]*

insert:

Palonosetron	Injection 250 micrograms (as hydrochloride) in 5 mL	Injection	Palonosetron Dr.Reddy's	RZ	MP	C5805	1	0	1	C(100)

[156] Schedule 1, Part 1, after entry for Palonosetron in the form Injection 250 micrograms (as hydrochloride) in 5 mL *[Brand: PALONOSETRON Medsurge]*

insert:

Palonosetron	Injection 250 micrograms (as hydrochloride) in 5 mL	Injection	PALONOSETRON Medsurge	DZ	MP	C5805	1	0	1	C(100)

[157] Schedule 1, Part 1, entry for Pantoprazole in the form Sachet containing granules 40 mg (as sodium sesquihydrate) *[Maximum Quantity: 120; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[158] Schedule 1, Part 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate) *[Brand: APO-Pantoprazole; Maximum Quantity: 120; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[159] Schedule 1, Part 1, after entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate) *[Brand: APO-Pantoprazole; Maximum Quantity: 120; Number of Repeats: 5]*

insert:

Pantoprazole	Tablet (enteric coated) 40 mg (as sodium sesquihydrate)	Oral	APX-PANTOPRAZOLE TW	MP NP	C8774 C8775	P8774 P8775	30	1	30
Pantoprazole	Tablet (enteric coated) 40 mg (as sodium sesquihydrate)	Oral	APX-PANTOPRAZOLE TW	MP NP	C8776 C8780 C8866	P8776 P8780 P8866	30	5	30
Pantoprazole	Tablet (enteric coated) 40 mg (as sodium sesquihydrate)	Oral	APX-PANTOPRAZOLE TW	MP	C11310	P11310	60	5	30
Pantoprazole	Tablet (enteric coated) 40 mg (as sodium sesquihydrate)	Oral	APX-PANTOPRAZOLE TW	MP NP	C15530 C15658 C15678	P15530 P15658 P15678	60	5	30
Pantoprazole	Tablet (enteric coated) 40 mg (as sodium sesquihydrate)	Oral	APX-PANTOPRAZOLE TW	MP	C15856	P15856	120	5	30

[160] **Schedule 1, Part 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate)** ***[Brand: BTC Pantoprazole; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[161] **Schedule 1, Part 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate)** ***[Brand: I-Pantoprazole; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[162] **Schedule 1, Part 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate)** ***[Brand: NOUMED PANTOPRAZOLE; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[163] **Schedule 1, Part 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate) *[Brand: Ozpan; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[164] **Schedule 1, Part 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate) *[Brand: Panthron; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[165] **Schedule 1, Part 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate) *[Brand: Pantoprazole APOTEX; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[166] **Schedule 1, Part 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate) *[Brand: Pantoprazole generichealth; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[167] **Schedule 1, Part 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate) *[Brand: Pantoprazole Sandoz; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[168] **Schedule 1, Part 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate) *[Brand: PANTOPRAZOLE-WGR; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[169] **Schedule 1, Part 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate) *[Brand: Salpraz; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[170] **Schedule 1, Part 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate) *[Brand: Somac; Maximum Quantity: 120; Number of* Repeats*: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[171] **Schedule 1, Part 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate) *[Brand: Sozol; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[172] **Schedule 1, Part 1, sixth entry for Pembrolizumab**

(a) *omit from the column headed "Circumstances":* **C14405**

(b) *omit from the column headed "Purposes":* **P14405**

[173] **Schedule 1, Part 1, after entry for Perindopril with amlodipine in the form Tablet containing 5 mg perindopril arginine with 10 mg amlodipine (as besilate) *[Brand: Coveram 5/10; Maximum Quantity: 60; Number of Repeats: 5]***

insert:

Perindopril with amlodipine	Tablet containing 5 mg perindopril arginine with 10 mg amlodipine (as besilate)	Oral	Perindopril Arginine/Amlodipine-WGR 5/10	WG	MP NP	C4398 C4418	P4398 P4418	30	5		30
Perindopril with amlodipine	Tablet containing 5 mg perindopril arginine with 10 mg amlodipine (as besilate)	Oral	Perindopril Arginine/Amlodipine-WGR 5/10	WG	MP NP	C14245 C14246	P14245 P14246	60	5		30

[174] Schedule 1, Part 1, after entry for Perindopril with amlodipine in the form Tablet containing 5 mg perindopril arginine with 5 mg amlodipine (as besilate) *[Brand: Coveram 5/5; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Perindopril with amlodipine	Tablet containing 5 mg perindopril arginine with 5 mg amlodipine (as besilate)	Oral	Perindopril Arginine/Amlodipine-WGR 5/5	WG	MP NP	C4398 C4418	P4398 P4418	30	5	30
Perindopril with amlodipine	Tablet containing 5 mg perindopril arginine with 5 mg amlodipine (as besilate)	Oral	Perindopril Arginine/Amlodipine-WGR 5/5	WG	MP NP	C14245 C14246	P14245 P14246	60	5	30

[175] Schedule 1, Part 1, after entry for Perindopril with amlodipine in the form Tablet containing 10 mg perindopril arginine with 10 mg amlodipine (as besilate) *[Brand: Coveram 10/10; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Perindopril with amlodipine	Tablet containing 10 mg perindopril arginine with 10 mg amlodipine (as besilate)	Oral	Perindopril Arginine/Amlodipine-WGR 10/10	WG	MP NP	C4398 C4418	P4398 P4418	30	5	30
Perindopril with amlodipine	Tablet containing 10 mg perindopril arginine with 10 mg amlodipine (as besilate)	Oral	Perindopril Arginine/Amlodipine-WGR 10/10	WG	MP NP	C14245 C14246	P14245 P14246	60	5	30

[176] Schedule 1, Part 1, after entry for Perindopril with amlodipine in the form Tablet containing 10 mg perindopril arginine with 5 mg amlodipine (as besilate) *[Brand: Coveram 10/5; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Perindopril with amlodipine	Tablet containing 10 mg perindopril arginine with 5 mg amlodipine (as besilate)	Oral	Perindopril Arginine/Amlodipine-WGR 10/5	WG	MP NP	C4398 C4418	P4398 P4418	30	5	30

Perindopril with amlodipine	Tablet containing 10 mg perindopril arginine with 5 mg amlodipine (as besilate)	Oral	Perindopril Arginine/Amlodipine-WGR 10/5	WG	MP NP	C14245 C14246 P14245 P14246	60	5		30	

[177] **Schedule 1, Part 1, entry for Phenelzine in the form Tablet 15 mg (as sulfate)**

omit from the column headed "Responsible Person": **LM** *substitute:* **NG**

[178] **Schedule 1, Part 1, entry for Prochlorperazine in each of the forms: Injection containing prochlorperazine mesilate 12.5 mg in 1 mL; and Tablet containing prochlorperazine maleate 5 mg *[Brand: Stemetil]***

omit from the column headed "Responsible Person": **SW** *substitute:* **IX**

[179] **Schedule 1, Part 1, entry for Rabeprazole in the form Tablet containing rabeprazole sodium 20 mg (enteric coated) *[Brand: APO-Rabeprazole; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[180] **Schedule 1, Part 1, entry for Rabeprazole in the form Tablet containing rabeprazole sodium 20 mg (enteric coated) *[Brand: Noumed Rabeprazole; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[181] **Schedule 1, Part 1, entry for Rabeprazole in the form Tablet containing rabeprazole sodium 20 mg (enteric coated) *[Brand: Parbezol; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[182] **Schedule 1, Part 1, entry for Rabeprazole in the form Tablet containing rabeprazole sodium 20 mg (enteric coated) *[Brand: Pariet; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[183] **Schedule 1, Part 1, entry for Rabeprazole in the form Tablet containing rabeprazole sodium 20 mg (enteric coated)** ***[Brand: Rabeprazole Mylan; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[184] **Schedule 1, Part 1, entry for Rabeprazole in the form Tablet containing rabeprazole sodium 20 mg (enteric coated)** ***[Brand: Rabeprazole Sandoz; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[185] **Schedule 1, Part 1, entry for Rabeprazole in the form Tablet containing rabeprazole sodium 20 mg (enteric coated)** ***[Brand: Rabeprazole SUN; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[186] **Schedule 1, Part 1, entry for Rabeprazole in the form Tablet containing rabeprazole sodium 20 mg (enteric coated)** ***[Brand: RABEPRAZOLE-WGR; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[187] **Schedule 1, Part 1, entry for Rabeprazole in the form Tablet containing rabeprazole sodium 20 mg (enteric coated)** ***[Brand: Zabep; Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C15531** *substitute:* **C15856**

(b) *omit from the column headed "Purposes":* **P15531** *substitute:* **P15856**

[188] **Schedule 1, Part 1, entries for Rivaroxaban**

substitute:

Rivaroxaban	Tablet 2.5 mg	Oral	Rivaroxaban-Teva	TB	MP NP	C10992	P10992	60	5	60
Rivaroxaban	Tablet 2.5 mg	Oral	Rivaroxaban-Teva	TB	MP	C11013	P11013	60	5	60

Rivaroxaban	Tablet 2.5 mg	Oral	Rivaroxaban-Teva	TB	MP NP	C14298	P14298	120	5		60
Rivaroxaban	Tablet 2.5 mg	Oral	Xarelto	AF	MP NP	C10992	P10992	60	5		60
Rivaroxaban	Tablet 2.5 mg	Oral	Xarelto	AF	MP	C11013	P11013	60	5		60
Rivaroxaban	Tablet 2.5 mg	Oral	Xarelto	AF	MP NP	C14298	P14298	120	5		60
Rivaroxaban	Tablet 10 mg	Oral	iXarola	AL	MP NP	C4402	P4402	30	0		30
Rivaroxaban	Tablet 10 mg	Oral	iXarola	AL	MP NP	C4132	P4132	30	5		30
Rivaroxaban	Tablet 10 mg	Oral	iXarola	AL	MP NP	C14300	P14300	60	5		30
Rivaroxaban	Tablet 10 mg	Oral	Rivaroxaban-Teva	TB	MP NP	C4402	P4402	30	0		30
Rivaroxaban	Tablet 10 mg	Oral	Rivaroxaban-Teva	TB	MP NP	C4132	P4132	30	5		30
Rivaroxaban	Tablet 10 mg	Oral	Rivaroxaban-Teva	TB	MP NP	C14300	P14300	60	5		30
Rivaroxaban	Tablet 10 mg	Oral	Xarelto	AF	MP NP	C4382	P4382	15	0		15
Rivaroxaban	Tablet 10 mg	Oral	Xarelto	AF	MP NP	C4402	P4402	15	1		15
Rivaroxaban	Tablet 10 mg	Oral	Xarelto	AF	MP NP	C4402	P4402	30	0		30
Rivaroxaban	Tablet 10 mg	Oral	Xarelto	AF	MP NP	C4132	P4132	30	5		30
Rivaroxaban	Tablet 10 mg	Oral	Xarelto	AF	MP NP	C14300	P14300	60	5		30
Rivaroxaban	Tablet 15 mg	Oral	iXarola	AL	MP NP	C4269	P4269	28	5		28
Rivaroxaban	Tablet 15 mg	Oral	iXarola	AL	MP NP	C14301	P14301	56	5		28
Rivaroxaban	Tablet 15 mg	Oral	Rivaroxaban-Teva	TB	MP NP	C4269	P4269	28	5		28
Rivaroxaban	Tablet 15 mg	Oral	Rivaroxaban-Teva	TB	MP NP	C4098 C4260	P4098 P4260	42	0		42

Rivaroxaban	Tablet 15 mg	Oral	Rivaroxaban-Teva	TB	MP NP	C14301	P14301	56	5	28
Rivaroxaban	Tablet 15 mg	Oral	Xarelto	AF	MP NP	C4269	P4269	28	5	28
Rivaroxaban	Tablet 15 mg	Oral	Xarelto	AF	MP NP	C4098 C4260	P4098 P4260	42	0	42
Rivaroxaban	Tablet 15 mg	Oral	Xarelto	AF	MP NP	C14301	P14301	56	5	28
Rivaroxaban	Tablet 20 mg	Oral	iXarola	AL	MP NP	C4099 C4132 C4268 C4269	P4099 P4132 P4268 P4269	28	5	28
Rivaroxaban	Tablet 20 mg	Oral	iXarola	AL	MP NP	C14264 C14300 C14301 C14318	P14264 P14300 P14301 P14318	56	5	28
Rivaroxaban	Tablet 20 mg	Oral	Rivaroxaban-Teva	TB	MP NP	C4099 C4132 C4268 C4269	P4099 P4132 P4268 P4269	28	5	28
Rivaroxaban	Tablet 20 mg	Oral	Rivaroxaban-Teva	TB	MP NP	C14264 C14300 C14301 C14318	P14264 P14300 P14301 P14318	56	5	28
Rivaroxaban	Tablet 20 mg	Oral	Xarelto	AF	MP NP	C4099 C4132 C4268 C4269	P4099 P4132 P4268 P4269	28	5	28
Rivaroxaban	Tablet 20 mg	Oral	Xarelto	AF	MP NP	C14264 C14300 C14301 C14318	P14264 P14300 P14301 P14318	56	5	28

[189] Schedule 1, Part 1, entry for Rizatriptan in the form Tablet (orally disintegrating) 10 mg (as benzoate)

(a) *omit:*

Rizatriptan	Tablet (orally disintegrating) 10 mg (as benzoate)	Oral	APO-Rizatriptan	TX	MP NP	C5708	4	5	2

(b) *omit:*

Rizatriptan	Tablet (orally disintegrating) 10 mg (as benzoate)	Oral	Rizatriptan ODT GH	GQ	MP NP	C5708	4	5	2

[190] Schedule 1, Part 1, after entry for Simvastatin in the form Tablet 10 mg *[Brand: Simvastatin Sandoz; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Simvastatin	Tablet 10 mg	Oral	SIMVASTATIN-WGR	WG	MP NP		30	5	30
Simvastatin	Tablet 10 mg	Oral	SIMVASTATIN-WGR	WG	MP NP	P14238	60	5	30

[191] Schedule 1, Part 1, after entry for Simvastatin in the form Tablet 20 mg *[Brand: Simvastatin Sandoz; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Simvastatin	Tablet 20 mg	Oral	SIMVASTATIN-WGR	WG	MP NP		30	5	30
Simvastatin	Tablet 20 mg	Oral	SIMVASTATIN-WGR	WG	MP NP	P14238	60	5	30

[192] Schedule 1, Part 1, after entry for Simvastatin in the form Tablet 40 mg *[Brand: Simvastatin Sandoz; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Simvastatin	Tablet 40 mg	Oral	SIMVASTATIN-WGR	WG	MP NP		30	5	30
Simvastatin	Tablet 40 mg	Oral	SIMVASTATIN-WGR	WG	MP NP	P14238	60	5	30

[193] Schedule 1, Part 1, after entry for Simvastatin in the form Tablet 80 mg *[Brand: Simvastatin Sandoz; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Simvastatin	Tablet 80 mg	Oral	SIMVASTATIN-WGR	WG	MP NP		30	5	30
Simvastatin	Tablet 80 mg	Oral	SIMVASTATIN-WGR	WG	MP NP	P14238	60	5	30

[194] Schedule 1, Part 1, after entry for Siponimod in the form Tablet 250 micrograms (as hemifumarate) *[Maximum Quantity: 120; Number of Repeats: 5]*

insert:

Siponimod	Tablet 1 mg (as hemifumarate)	Oral	Mayzent	NV	MP	C10953 C10955	28	5	28	

[195] Schedule 1, Part 1, after entry for Tenofovir with emtricitabine in the form Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg *[Brand: TENOFOVIR/EMTRICITABINE 300/200 ARX; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg (S19A)	Oral	Emtricitabine and Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets (Laurus Labs, USA)	KQ	MP NP	C11143	30	2	30	
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg (S19A)	Oral	Emtricitabine and Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets (Laurus Labs, USA)	KQ	MP NP	C6985 C6986	60	5	30	C(100)

[196] Schedule 1, Part 1, entry for Tenofovir with emtricitabine

omit:

Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg	Oral	Tenofovir EMT GH	GQ	MP NP	C11143	P11143	30	2	30	
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg	Oral	Tenofovir EMT GH	GQ	MP NP	C6985 C6986	P6985 P6986	60	5	30	C(100)

[197] Schedule 1, Part 1, after entry for Timolol in the form Eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL (S19A)

insert:

Timolol	Eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL - (Timoptol-LA) (S19A)	Application to the eye	Timoptol-LA 0.5 % (Santen Oy, Finland)	LM	MP AO			1	5	1

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

(a) *omit from the column headed "Circumstances":* **C14720**

(b) *omit from the column headed "Purposes":* **P14720**

[199] 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":* **C15128**

(b) *omit from the column headed "Purposes":* **P15128**

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

omit:

Valaciclovir	Tablet 500 mg (as hydrochloride)	Oral	Valacor 500	CR	MP NP	C5940 C5961	P5940 P5961	30	5	30
Valaciclovir	Tablet 500 mg (as hydrochloride)	Oral	Valacor 500	CR	MP NP	C5962 C5968	P5962 P5968	42	0	42

[201] Schedule 1, Part 1, after entry for Varenicline in the form Box containing 11 tablets 0.5 mg (as tartrate) and 14 tablets 1 mg (as tartrate) in the first pack and 28 tablets 1 mg (as tartrate) in the second pack *[Brand: VARENAPIX]*

insert:

Varenicline	Box containing 11 tablets 0.5 mg (as tartrate) and 14 tablets 1 mg (as tartrate) in the first pack and 28 tablets 1 mg (as tartrate) in the second pack	Oral	Varenicline Viatris	AF	MP NP	C6871		1	0	1

[202] **Schedule 1, Part 1, entry for Vedolizumab in the form Injection 108 mg in 0.68 mL single use pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances":* **C12242 C12576**

(b) *insert in numerical order in the column headed "Circumstances":* **C15931 C15944**

(c) *omit from the column headed "Purposes":* **P12242 P12576**

(d) *insert in numerical order in the column headed "Purposes":* **P15931 P15944**

[203] **Schedule 1, Part 1, entry for Vedolizumab in the form Injection 108 mg in 0.68 mL single use pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C12078 C12178** *substitute:* **C15942 C15943**

(b) *omit from the column headed "Purposes":* **P12078 P12178** *substitute:* **P15942 P15943**

[204] **Schedule 1, Part 1, entry for Venetoclax in the form Pack containing 14 tablets venetoclax 10 mg and 7 tablets venetoclax 50 mg and 7 tablets venetoclax 100 mg and 14 tablets venetoclax 100 mg**

insert in numerical order in the column headed "Circumstances": **C15836 C15905**

[205] **Schedule 1, Part 1, entry for Venetoclax in the form Tablet 100 mg *[Maximum Quantity: 120; Number of Repeats: 4]***

(a) *insert in numerical order in the column headed "Circumstances":* **C15836 C15907**

(b) *insert in numerical order in the column headed "Purposes":* **P15836 P15907**

[206] **Schedule 1, Part 1, entry for Venetoclax in the form Tablet 100 mg *[Maximum Quantity: 120; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C11073**

(b) *insert in numerical order in the column headed "Circumstances":* **C15904 C15906**

(c) *omit from the column headed "Purposes":* **P11073**

(d) *insert in numerical order in the column headed "Purposes":* **P15904 P15906**

[207] **Schedule 1, Part 1, entry for Zoledronic acid in the form Solution for I.V. infusion 5 mg (as monohydrate) in 100 mL**

omit:

Zoledronic acid	Solution for I.V. infusion 5 mg (as monohydrate) in 100 mL	Injection	Zoledronic Acid SUN	RA	MP	C5710 C6308 C6313 C6318	1	0	1

[208] **Schedule 1, Part 2, omit entries for Estradiol**

[209] **Schedule 1, Part 2, omit entry for Fluorometholone**

[210] **Schedule 1, Part 2, entry for Niraparib in the form Capsule 100 mg (as tosilate monohydrate) *[Pack Quantity: 56]***

omit from the column headed "Manner of Administration": **Orald** *substitute:* **Oral**

[211] **Schedule 1, Part 2, omit entry for Somatropin**

[212] **Schedule 3, details relevant for Responsible Person code BX**

omit from the column headed "Responsible Person": **Baxter Healthcare Pty Limited** *substitute:* **BAXTER HEALTHCARE PTY LTD**

[213] **Schedule 3, details relevant for Responsible Person code IU**

omit from the column headed "Responsible Person": **AU Pharma Pty Ltd** *substitute:* **AUPHARMA PTY LTD**

[214] **Schedule 3, after details relevant for Responsible Person code NF**

insert:

NG	NEON HEALTHCARE PTY LIMITED	57 670 586 526

[215] **Schedule 3, details relevant for Responsible Person code NP**

omit from the column headed "Responsible Person": **Nice-Pak Products Pty. Ltd** *substitute:* **NICE-PAK PRODUCTS PTY. LTD.**

[216] **Schedule 3 after details relevant for Responsible Person code VO**

insert:

VQ	Novartis Pharmaceuticals Australia Pty Limited	18 004 244 160

[217] **Schedule 4, Part 1, entry for Circumstances Code "C9064"**

insert in alphabetical order in the column headed "Listed Drug": **Bimekizumab**

[218] **Schedule 4, Part 1, entry for Circumstances Code "C10434"**

insert in alphabetical order in the column headed "Listed Drug": **Bimekizumab**

[219] **Schedule 4, Part 1, omit entry for Circumstances Code "C11073"**

[220] **Schedule 4, Part 1, omit entry for Circumstances Code "C12078"**

[221] **Schedule 4, Part 1, omit entry for Circumstances Code "C12178"**

[222] **Schedule 4, Part 1, omit entry for Circumstances Code "C12242"**

[223] **Schedule 4, Part 1, omit entry for Circumstances Code "C12576"**

[224] **Schedule 4, Part 1, omit entry for Circumstances Code "C13070"**

[225] **Schedule 4, Part 1, entry for Circumstances Code "C14217"**

insert in alphabetical order in the column headed "Listed Drug": **Bimekizumab**

[226] **Schedule 4, Part 1, omit entry for Circumstances Code "C14405"**

[227] **Schedule 4, Part 1, omit entry for Circumstances Code "C14412"**

[228] **Schedule 4, Part 1, omit entry for Circumstances Code "C14720"**

[229] **Schedule 4, Part 1, omit entry for Circumstances Code "C14726"**

[230] **Schedule 4, Part 1, omit entry for Circumstances Code "C14828"**

[231] **Schedule 4, Part 1, omit entry for Circumstances Code "C14832"**

[232] **Schedule 4, Part 1, omit entry for Circumstances Code "C15128"**

[233] **Schedule 4, Part 1, entry for Circumstances Code "C15140"**

insert in alphabetical order in the column headed "Listed Drug": **Bimekizumab**

[234] **Schedule 4, Part 1, entry for Circumstances Code "C15149"**

insert in alphabetical order in the column headed "Listed Drug": **Bimekizumab**

[235] **Schedule 4, Part 1, entry for Circumstances Code "C15150"**

insert in alphabetical order in the column headed "Listed Drug": **Bimekizumab**

[236] **Schedule 4, Part 1, omit entry for Circumstances Code "C15341"**

[237] **Schedule 4, Part 1, omit entry for Circumstances Code "C15433"**

[238] **Schedule 4, Part 1, omit entry for Circumstances Code "C15531"**

[239] **Schedule 4, Part 1, omit entry for Circumstances Code "C15705"**

[240] **Schedule 4, Part 1, omit entry for Circumstances Code "C15797"**

[241] Schedule 4, Part 1, after entry for Circumstances Code "C15832"

insert:

C15836	P15836	CN15836	Venetoclax	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply of first-line therapy Patient must have received non-PBS-subsidised treatment with ibrutinib for this condition prior to 1 October 2024; AND Patient must not have developed disease progression while receiving treatment for this condition; AND The treatment must be in combination with ibrutinib (refer to Product Information for timing of ibrutinib and venetoclax doses). 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 next relevant treatment phase. A patient may also qualify for treatment under this listing if they have previously received non-PBS-subsidised treatment with venetoclax for this condition prior to 1 October 2024 from Cycle 4.	Compliance with Authority Required procedures
C15851	P15851	CN15851	Etrasimod	Moderate to severe ulcerative colitis Initial treatment - Initial 1 (new patient) 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).	Compliance with Written Authority Required procedures

				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 authority application must be made in writing and must include: (1) details of the proposed prescription; 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.	

C15853	P15853	CN15853	Etrasimod	Moderate to severe ulcerative colitis Transitioning from non-PBS to PBS-subsided treatment - Grandfather arrangements Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 October 2024; 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. 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	Compliance with Written Authority Required procedures

				gastroenterology (code 82)]. The authority application must be made in writing and must include: (1) details of the proposed prescription; 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; and (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.	
C15854	P15854	CN15854	Fluticasone propionate	Asthma The treatment must not be a PBS benefit where this 50 microgram strength is being initiated in a patient over the age of 6.00 years; AND The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	Compliance with Authority Required procedures - Streamlined Authority Code 15854
C15856	P15856	CN15856	Esomeprazole Lansoprazole Omeprazole Pantoprazole Rabeprazole	Complex gastro-oesophageal reflux disease (GORD) One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Must be treated by a gastroenterologist; OR Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR Must be treated by a medical practitioner who has consulted at least one of the above	Compliance with Authority Required procedures

				mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; OR Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes. The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI; AND Patient must must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 2 packs per dispensing. Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.	
C15857	P15857	CN15857	Bimekizumab	Ankylosing spondylitis Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND	Compliance with Written Authority Required procedures

				Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) details of the proposed prescription; 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). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and	

				(ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C15859	P15859	CN15859	Bimekizumab	Non-radiographic axial spondyloarthritis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 October 2024; AND Patient must have demonstrated an adequate response following at least 12 weeks of non-PBS-subsidised treatment with this drug for this condition; AND The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent);	Compliance with Written Authority Required procedures

				AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this	

				course of treatment in this treatment cycle. The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The baseline BASDAI score and CRP level must also be documented in the patient's medical records.	
C15861	P15861	CN15861	Ibrutinib	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) First continuing treatment (treatment cycles 4 to 9 inclusive) of first-line therapy Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with venetoclax (refer to Product Information for timing of ibrutinib and venetoclax doses); AND The treatment must cease upon disease progression. There are more ibrutinib capsules (or tablets) in a pack than is required for the completion of a treatment cycle. The patient must not discard any remaining capsules (or tablets) after the completion of any treatment cycle as these capsules (or tablets) will be required for the doses in the final treatment cycle (i.e. treatment cycle 15).	Compliance with Authority Required procedures
C15863	P15863	CN15863	Ibrutinib	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Second and final continuing treatment (treatment cycles 10 to 15 inclusive) of first-line therapy Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with venetoclax (refer to Product Information for timing of ibrutinib and venetoclax doses); AND The treatment must cease upon disease progression; OR The treatment must cease upon completion of 15 cycles of treatment with this drug for this condition, whichever comes first. There are more ibrutinib capsules (or tablets) in a pack than is required for the completion of a treatment cycle. The patient must not discard any remaining capsules (or tablets) after the completion of any treatment cycle as these capsules (or tablets) will be required for the doses in the final treatment cycle (i.e. treatment cycle 15).	Compliance with Authority Required procedures
C15864	P15864	CN15864	Ibrutinib	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Initial treatment in first-line therapy (treatment cycles 1 to 3 inclusive) The condition must be untreated with drug treatment at the time of the first dose of this	Compliance with Authority Required procedures

				drug; OR Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL; AND The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND The treatment must be in combination with venetoclax (refer to Product Information for timing of ibrutinib and venetoclax doses). There are more ibrutinib capsules (or tablets) in a pack than is required for the completion of a treatment cycle. The patient must not discard any remaining capsules (or tablets) after the completion of any treatment cycle as these capsules (or tablets) will be required for the doses in the final treatment cycle (i.e. treatment cycle 15).	
C15874	P15874	CN15874	Bimekizumab	Ankylosing spondylitis Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age.	Compliance with Written Authority Required procedures

				Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) details of the proposed prescription; 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). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application 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 biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C15886	P15886	CN15886	Dupilumab	Uncontrolled severe asthma Initial treatment - Initial 2 (Change of treatment) Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma. Patient must be under the care of the same physician for at least 6 months; OR Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND Patient must have received prior PBS-subsidised treatment with a biological medicine	Compliance with Written Authority Required procedures

				for severe asthma in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE; AND Patient must not receive more than 32 weeks of treatment under this restriction; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma. Patient must be aged 12 years or older. An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine. An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed. This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine. At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 400 mg as an initial dose, followed by 200 mg every 2 weeks	

				thereafter. A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts. A multidisciplinary severe asthma clinic team comprises of: (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator. The authority application must be made in writing and must include: (1) details of the proposed prescription; 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). The following must be provided at the time of application and documented in the patient's medical records: (a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and (b) details (treatment, date of commencement, duration of therapy) of prior biological medicine treatment; and (c) if applicable, the eosinophil count and date; and (d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and (e) if applicable, the IgE result and date; and (f) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).	
C15887	P15887	CN15887	Etrasimod	Moderate to severe ulcerative colitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) 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). Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in	Compliance with Written Authority Required procedures

				gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. The authority application must be made in writing and must include: (1) details of the proposed prescription; 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 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.	
C15888	P15888	CN15888	Etrasimod	Moderate to severe ulcerative colitis Continuing treatment 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. 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	Compliance with Authority Required procedures

				gastroenterology (code 82)]. 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.	
C15889	P15889	CN15889	Icosapent ethyl	Established atherosclerotic cardiovascular disease with hypertriglyceridaemia Initial treatment The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have at least one of (i) coronary artery disease, (ii) cerebrovascular or carotid disease, (iii) peripheral arterial disease; AND Patient must be treated with a stable dose of a HMG CoA reductase inhibitor (statin) to achieve target secondary prevention LDL-c levels for at least 12 consecutive weeks; OR Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have LDL cholesterol level between 1.0 millimoles per litre and	Compliance with Authority Required procedures - Streamlined Authority Code 15889

				2.6 millimoles per litre; OR Patient must have a non-HDL cholesterol between 1.5 millimoles per litre and 3.5 millimoles per litre if LDL cannot be measured/detected; AND Patient must have fasting triglyceride level between 1.7 millimoles per litre and 5.6 millimoles per litre. The qualifying fasting triglyceride level and LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, dietary therapy and exercise should be documented in the patient's medical records and must be no more than 8 weeks old. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. Atherosclerotic cardiovascular disease is defined as: (i) Documented coronary artery disease (CAD); one or more of the following primary criteria must have been satisfied: a) Documented multi-vessel CAD (at least 50% stenosis in at least two major epicardial coronary arteries, with or without antecedent revascularisation). b) Documented prior MI. c) Hospitalisation for high-risk non-ST-segment elevation acute coronary syndrome, with objective evidence of ischemia: ST-segment deviation or biomarker positivity. (ii) Documented cerebrovascular or carotid disease; one of the following primary criteria must have been satisfied: a) Documented prior ischemic stroke. b) Symptomatic carotid artery disease with at least 50% carotid arterial stenosis. c) Asymptomatic carotid artery disease with at least 70% carotid arterial stenosis per angiography or duplex ultrasound. d) History of carotid revascularisation (catheter-based or surgical). (iii) Documented peripheral arterial disease; one or more of the following primary criteria must have been satisfied: a) Ankle brachial index (ABI) less than 0.9 with symptoms of intermittent claudication. b) History of aorto-iliac or peripheral arterial intervention (catheter-based or surgical).	

C15890	P15890	CN15890	Bimekizumab	Ankylosing spondylitis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 October 2024; AND Patient must have had at least 2 of the following prior to commencing non-PBS-subsidised treatment with this drug for this condition: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months prior to commencing non-PBS-subsidised treatment; AND Patient must have demonstrated an adequate response after 16 weeks of treatment if the patient has been treated with this drug for this condition for 16 weeks or longer; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response to NSAIDs and must have been demonstrated prior to initiation of non-PBS subsidised treatment with this biological medicine for this condition: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-	Compliance with Written Authority Required procedures

				10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must have been determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. If the above requirement to demonstrate an elevated ESR or CRP could not be met, the application must state the reason this criterion could not be satisfied. The authority application must be made in writing and must include: (1) details of the proposed prescription; 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). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) baseline and current BASDAI scores; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. To demonstrate a response to treatment the application 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 biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.	

				Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C15891	P15891	CN15891	Bimekizumab	Non-radiographic axial spondyloarthritis Initial treatment - Initial 1 (New patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND The treatment must not exceed a maximum of 16 weeks with this drug under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-	Compliance with Written Authority Required procedures

				approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The baseline BASDAI score and CRP level must also be documented in the patient's medical records.	
C15892	P15892	CN15892	Ibrutinib	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply of first-line therapy Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 October 2024; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND	Compliance with Authority Required procedures

				The condition must have been untreated with drug treatment at the time of the first dose of this drug; OR Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line treatment of CLL/SLL at the time of receiving non-PBS-subsidised treatment with this drug for this condition; AND The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND The treatment must be in combination with venetoclax (refer to Product Information for timing of ibrutinib and venetoclax doses). 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 next relevant treatment phase. There are more ibrutinib capsules (or tablets) in a pack than is required for the completion of a treatment cycle. The patient must not discard any remaining capsules (or tablets) after the completion of any treatment cycle as these capsules (or tablets) will be required for the doses in the final treatment cycle (i.e. treatment cycle 15).	
C15894	P15894	CN15894	Avacopan	Anti-neutrophil cytoplasmic autoantibody (ANCA) associated vasculitis Induction treatment The condition must be severe granulomatosis with polyangiitis; OR The condition must be severe microscopic polyangiitis; AND The condition must be active at the time of the first prescription for this drug per treatment cycle; AND Patient must have ANCA associated vasculitis that is either: (i) organ-threatening, (ii) life-threatening disease; AND Patient must be undergoing concomitant therapy with at least another drug therapy as part of a regimen specified in this drug's approved Product Information; AND Patient must not receive more than 12 months of PBS-subsidised treatment with this drug per induction. A prescriber may apply for more than one induction treatment for their patient	Compliance with Authority Required procedures
C15902	P15902	CN15902	Bimekizumab	Severe psoriatic arthritis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug;	Compliance with Written Authority Required procedures

				AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient 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.	
C15903	P15903	CN15903	Bimekizumab	Severe psoriatic arthritis Continuing treatment - balance of supply 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. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.	Compliance with Authority Required procedures
C15904	P15904	CN15904	Venetoclax	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Second and final continuing treatment prescription (treatment cycles 10 to 15 inclusive) of first-line therapy Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with ibrutinib (refer to Product Information for timing of ibrutinib and venetoclax doses); AND The treatment must cease upon disease progression; OR The treatment must cease upon completion of 12 cycles of treatment with this drug for this condition, whichever comes first.	Compliance with Authority Required procedures
C15905	P15905	CN15905	Venetoclax	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Initial treatment in first-line therapy with ibrutinib - Dose titration (cycle 4) The condition must be untreated with venetoclax at the time of the first dose of this drug; AND The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND The treatment must be in combination with ibrutinib (refer to Product Information for timing of ibrutinib and venetoclax doses).	Compliance with Authority Required procedures

C15906	P15906	CN15906	Venetoclax	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Second and final continuing treatment prescription (treatment cycles 7 to 12 inclusive) of first-line therapy Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must cease upon disease progression; OR The treatment must cease upon completion of 12 cycles of treatment with this drug for this condition, whichever comes first; AND The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses).	Compliance with Authority Required procedures
C15907	P15907	CN15907	Venetoclax	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) First continuing treatment (treatment cycles 5 to 9 inclusive) of first-line therapy Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with ibrutinib (refer to Product Information for timing of ibrutinib and venetoclax doses); AND The treatment must cease upon disease progression.	Compliance with Authority Required procedures
C15916	P15916	CN15916	Bimekizumab	Severe psoriatic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) 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 The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must be at least 18 years of age.	Compliance with Written Authority Required procedures

				Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for 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. To demonstrate a response to treatment the application 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 biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. 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.	
C15917	P15917	CN15917	Bimekizumab	Severe psoriatic arthritis	Compliance with Written

				Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have received treatment with this drug for this PBS indication prior to 1 October 2024; AND Patient must be receiving treatment with this drug for this condition at the time of application; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug for this condition if the patient has received non-PBS-subsidised treatment for at least 12 weeks; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must be at least 18 years of age. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of	Authority Required procedures

				passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include: (a) details of the proposed prescription; 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). (c) the date of commencement of this drug; and (d) results of the baseline patient assessment prior to initiation of non-PBS-subsidised therapy with this drug. The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all continuing treatment applications. 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. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the	

				necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C15918	P15918	CN15918	Aflibercept	Subfoveal choroidal neovascularisation (CNV) Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. The condition must be due to age-related macular degeneration (AMD); AND The condition must be diagnosed by optical coherence tomography; OR The condition must be diagnosed by fluorescein angiography; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. If the application is submitted through HPOS form upload or mail, it must include: (a) details of the proposed prescription; 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). All reports must be documented in the patient's medical records.	Compliance with Written Authority Required procedures
C15919	P15919	CN15919	Aflibercept	Diabetic macular oedema (DMO) Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Patient must have visual impairment due to diabetic macular oedema; AND Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment; AND The condition must be diagnosed by optical coherence tomography; OR	Compliance with Written Authority Required procedures

				The condition must be diagnosed by fluorescein angiography; AND The treatment must be as monotherapy; OR The treatment must be in combination with laser photocoagulation; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. If the application is submitted through HPOS form upload or mail, it must include: (a) details of the proposed prescription; 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). All reports must be documented in the patient's medical records.	
C15924	P15924	CN15924	Dupilumab	Uncontrolled severe asthma Initial treatment 1 - (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy) Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma. Patient must be under the care of the same physician for at least 6 months; OR Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma; AND Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF)	Compliance with Written Authority Required procedures

				variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records; AND Patient must have a duration of asthma of at least 1 year; AND Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; OR Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; OR Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured in the last 12 months that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE; AND Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records; AND Patient must not receive more than 32 weeks of treatment under this restriction; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma. Patient must be aged 12 years or older. Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application. The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application: (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this	

				drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed. This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. 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 the same treatment cycle. A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle. There is no limit to the number of treatment cycles that a patient may undertake in their lifetime. A multidisciplinary severe asthma clinic team comprises of: (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator. At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 400 mg as an initial dose, followed by 200 mg every 2 weeks thereafter. A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts. The authority application must be made in writing and must include: (1) details of the proposed prescription; 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). The following must be provided at the time of application and documented in the patient's medical records: (a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and (b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the	

				relevant TGA-approved Product Information; and (c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (d) Asthma Control Questionnaire (ACQ-5) score; and (e) if applicable, the eosinophil count and date; and (f) if applicable, the IgE result and date.	
C15926	P15926	CN15926	Etrasimod	Moderate to severe ulcerative colitis Continuing treatment - balance of supply 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. 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
C15927	P15927	CN15927	Icosapent ethyl	Established atherosclerotic cardiovascular disease with hypertriglyceridaemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in conjunction with dietary therapy and exercise; AND The treatment must be co-administered with a HMG CoA reductase inhibitor (statin), unless the patient is contraindicated to statins or has developed statin related adverse events necessitating withdrawal of statin treatment.	Compliance with Authority Required procedures - Streamlined Authority Code 15927
C15928	P15928	CN15928	Aflibercept	Diabetic macular oedema (DMO) Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication for the same eye prior to 1 October 2024; AND Patient must have visual impairment due to diabetic macular oedema; AND Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen	Compliance with Written Authority Required procedures

				equivalent 20/32 to 20/160), in the eye proposed for treatment; AND The condition must be diagnosed by optical coherence tomography; OR The condition must be diagnosed by fluorescein angiography; AND The treatment must be as monotherapy; OR The treatment must be in combination with laser photocoagulation; AND The treatment must be the sole PBS-subsidised therapy for this condition. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. If the application is submitted through HPOS form upload or mail, it must include: (a) details of the proposed prescription; 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). All reports must be documented in the patient's medical records.	
C15931	P15931	CN15931	Vedolizumab	Severe Crohn disease Initial treatment with subcutaneous form 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 at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 1 (new patient); OR Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years); OR Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years); OR Patient must have a concurrent authority application for the intravenous infusion for this condition under either Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).	Compliance with Written Authority Required procedures

				Patient must be at least 18 years of age. Where two initial doses of vedolizumab (at weeks 0 and 2) are administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. The maximum listed quantity and 2 repeats should be requested to provide for weeks 6, 8, 10, 12, 14 and 16. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity with no repeats should be requested to provide for weeks 14 and 16. The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. 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. Where four initial doses of vedolizumab (at weeks 0, 2, 6 and 10) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (4 weeks after the fourth dose). A maximum quantity with no repeats should be requested to provide for weeks 14 and 16.	
C15936	P15936	CN15936	Esomeprazole	Complex gastro-oesophageal reflux disease (GORD) One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Must be treated by a gastroenterologist; OR Must be treated by a surgeon with expertise in the upper gastrointestinal tract.	Compliance with Authority Required procedures

				The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI; AND Patient must have symptoms inadequately controlled with each of: (i) a high dose proton pump inhibitor (PPI) administered once daily, (ii) a standard dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR Patient must be assessed for the risks/benefits of a step-down in dosing from a high dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 2 packs per dispensing. Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.	
C15937	P15937	CN15937	Bimekizumab	Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline.	Compliance with Written Authority Required procedures

				Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. 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 these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C15938	P15938	CN15938	Bimekizumab	Ankylosing spondylitis Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) details of the proposed prescription; 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).	Compliance with Written Authority Required procedures

				An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application 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 biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C15939	P15939	CN15939	Bimekizumab	Ankylosing spondylitis 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	Compliance with Authority Required procedures

				Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	
C15940	P15940	CN15940	Bimekizumab	Severe psoriatic arthritis Initial treatment - Initial 1 (new patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must be at least 18 years of age. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:	Compliance with Written Authority Required procedures

				an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C15942	P15942	CN15942	Vedolizumab	Severe Crohn disease Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form 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	Compliance with Written Authority Required procedures

				gastroenterology (code 82)]. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab intravenous form continuing treatment restriction; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; OR Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form. Patient must be at least 18 years of age. Applications for authorisation must be made in writing and must include: (a) details of the proposed prescription; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the	

				patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. 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. At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction. Up to a maximum of 5 repeats will be authorised. If fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone or electronically via the Online PBS Authorities system and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will immediate assessment approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.	
C15943	P15943	CN15943	Vedolizumab	Moderate to severe ulcerative colitis Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form 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; OR Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab intravenous form continuing treatment restriction; AND Patient must not receive more than 24 weeks of treatment under this restriction; 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	Compliance with Authority Required procedures

				1 while receiving treatment with this drug; OR Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form. 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. Up to a maximum of 5 repeats will be authorised. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C15944	P15944	CN15944	Vedolizumab	Moderate to severe ulcerative colitis Initial treatment with subcutaneous form 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 at least 2 of the 3 initial intravenous infusions with this drug	Compliance with Written Authority Required procedures

				for this condition at weeks 0, 2 and 6 under Initial 1 (new patient); OR Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years); OR Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years); OR Patient must have a concurrent authority application for the intravenous infusion for this condition under either Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years). Patient must be at least 18 years of age. Where two initial doses of vedolizumab (at weeks 0 and 2) are administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. The maximum listed quantity and 2 repeats should be requested to provide for weeks 6, 8, 10, 12, 14 and 16. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity with no repeats should be requested to provide for weeks 14 and 16. The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. 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.	

C15946	P15946	CN15946	Etrasimod	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) 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. 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 authority application must be made in writing and must include: (1) details of the proposed prescription; 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. 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	Compliance with Written Authority Required procedures

				criterion.	
C15947	P15947	CN15947	Etrasimod	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 Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a 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
C15949	P15949	CN15949	Bimekizumab	Ankylosing spondylitis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	Compliance with Authority Required procedures
C15950	P15950	CN15950	Bimekizumab	Severe psoriatic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND	Compliance with Written Authority Required procedures

				Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who has received PBS-subsidised treatment with this drug and 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 treatment with this drug, within the timeframes specified below. To demonstrate a response to treatment the application 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 biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. 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.	
C15952	P15952	CN15952	Aflibercept	Subfoveal choroidal neovascularisation (CNV) Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication for the same eye prior to 1 October 2024; AND The condition must be due to age-related macular degeneration (AMD); AND The condition must be diagnosed by optical coherence tomography; OR The condition must be diagnosed by fluorescein angiography; AND The treatment must be the sole PBS-subsidised therapy for this condition. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. If the application is submitted through HPOS form upload or mail, it must include: (a) details of the proposed prescription; 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). All reports must be documented in the patient's medical records.	Compliance with Written Authority Required procedures

[242] Schedule 5, entry for Abacavir with lamivudine

omit from the column headed "Brand": **ABACAVIR/LAMIVUDINE 600/300 SUN**

[243] Schedule 5, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[GRP-25060]*

insert in alphabetical order in the column headed "Brand": **Hadlima**

[244] **Schedule 5, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[GRP-25060]***

omit from the column headed "Brand": **Idacio**

[245] **Schedule 5, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[GRP-25058]***

insert in alphabetical order in the column headed "Brand": **Hadlima**

[246] **Schedule 5, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[GRP-25058]***

omit from the column headed "Brand": **Idacio**

[247] **Schedule 5, after entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[GRP-25058]***

insert:

Adalimumab	GRP-29151	Injection 80 mg in 0.8 mL pre-filled pen	Injection	Humira Yuflyma
Adalimumab	GRP-29152	Injection 80 mg in 0.8 mL pre-filled syringe	Injection	Humira Yuflyma

[248] **Schedule 5, entry for Amoxicillin in the form Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL**

substitute:

Amoxicillin	GRP-20061	Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL	Oral	Amoxil Amoxycillin Sandoz APO-Amoxycillin NOUMED AMOXICILLIN

[249] **Schedule 5, entry for Amoxicillin in the form Capsule 500 mg (as trihydrate)**

omit from the column headed "Brand": **NOUMED AMOXICILLIN**

[250] **Schedule 5, entry for Aripiprazole in each of the forms: Tablet 10 mg; Tablet 15 mg; Tablet 30 mg; and Tablet 20 mg**

omit from the column headed "Brand": **Tevaripiprazole**

[251] **Schedule 5, entry for Atorvastatin in the form Tablet 80 mg (as calcium)**

omit from the column headed "Brand": **Atorvastatin GH**

[252] **Schedule 5, entry for Azithromycin in the form Tablet 500 mg (as dihydrate)**

omit from the column headed "Brand": **Azithromycin Mylan**

[253] **Schedule 5, entry for Budesonide with formoterol in each of the forms: Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses; and Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses**

omit from the column headed "Brand": **BiResp Spiromax**

[254] **Schedule 5, entry for Carbamazepine in each of the forms: Tablet 200 mg; and Tablet 100 mg**

insert in alphabetical order in the column headed "Brand": **AVLOIRE**

[255] **Schedule 5, entry for Celecoxib in each of the forms: Capsule 100 mg; and Capsule 200 mg**

insert in alphabetical order in the column headed "Brand": **Blooms Celecoxib**

[256] **Schedule 5, entry for Ciprofloxacin in the form Tablet 500 mg (as hydrochloride)**

omit from the column headed "Brand": **Cifran**

[257] **Schedule 5, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg**

omit from the column headed "Brand": **Pharmacor Cyproterone 50**

[258] **Schedule 5, entry for Cyproterone in the form Tablet containing cyproterone acetate 100 mg**

omit from the column headed "Brand": **Pharmacor Cyproterone 100**

[259] **Schedule 5, entry for Dasatinib in each of the forms: Tablet 70 mg; Tablet 50 mg; Tablet 20 mg; and Tablet 100 mg**

omit from the column headed "Brand": **TE-DASATINIB**

[260] **Schedule 5, entry for Dicloxacillin in the form Capsule 500 mg (as sodium)**

omit from the column headed "Brand": **Dicloxacillin Mylan 500**

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

omit from the column headed "Brand": **NOUMED DONEPEZIL**

[262] **Schedule 5, entry for Duloxetine in the form Capsule 30 mg (as hydrochloride)**

omit from the column headed "Brand": **Tixol** *substitute:* **Tixol 30**

[263] **Schedule 5, entry for Duloxetine in the form Capsule 60 mg (as hydrochloride)**

omit from the column headed "Brand": **Tixol** *substitute:* **Tixol 60**

[264] **Schedule 5, entry for Dutasteride with tamsulosin**

insert in alphabetical order in the column headed "Brand": **DUTATAM 500/400**

[265] **Schedule 5, entry for Enalapril in the form Tablet containing enalapril maleate 20 mg**

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

[266] **Schedule 5, entry for Entecavir in the form Tablet 0.5 mg (as monohydrate)**

omit from the column headed "Brand": **Entecavir Mylan**

[267] **Schedule 5, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate)**

omit from the column headed "Brand": **NOUMED ESOMEPRAZOLE**

[268] **Schedule 5, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate)**

omit from the column headed "Brand": **NOUMED ESOMEPRAZOLE**

[269] **Schedule 5, entry for Fluconazole in the form Capsule 200 mg**

insert in alphabetical order in the column headed "Brand": **APO-Fluconazole**

[270] **Schedule 5, entry for Gabapentin in the form Capsule 400 mg**

substitute:

Gabapentin	GRP-20293	Capsule 400 mg	Oral	APX-Gabapentin Gabacor Gabapentin Sandoz GABAPENTIN-WGR GAPENTIN Neurontin Nupentin 400

[271] **Schedule 5, entry for Gabapentin in the form Capsule 300 mg**

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

[272] **Schedule 5, entry for Imatinib in the form Tablet 100 mg (as mesilate)**

insert in alphabetical order in the column headed "Brand": **Imanib**

[273] **Schedule 5, entry for Imatinib in the form Tablet 400 mg (as mesilate)**

insert in alphabetical order in the column headed "Brand": **Imanib**

[274] **Schedule 5, entry for Lamivudine in the form Tablet 150 mg**

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

[275] **Schedule 5, entry for Lisinopril in the form Tablet 20 mg**

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

[276] **Schedule 5, entry for Meloxicam in the form Tablet 15 mg**

omit from the column headed "Brand": **Pharmacor Meloxicam 15**

[277] **Schedule 5, entry for Meloxicam in the form Tablet 7.5 mg**

omit from the column headed "Brand": **Pharmacor Meloxicam 7.5**

[278] **Schedule 5, entry for Metformin in the form Tablet (extended release) containing metformin hydrochloride 1 g**

insert in alphabetical order in the column headed "Brand": **Diaformin Alphapharm XR**

[279] **Schedule 5, entry for Metformin in the form Tablet (extended release) containing metformin hydrochloride 500 mg**

insert in alphabetical order in the column headed "Brand": **Diaformin Alphapharm XR**

[280] **Schedule 5, after entry for Metoprolol succinate in the form Tablet 23.75 mg (controlled release)**

insert:

Metronidazole	GRP-20031	Tablet 200 mg	Oral	METRONIDAMED Metrogyl 200

[281] **Schedule 5, entry for Metronidazole in the form Tablet 400 mg**

insert in alphabetical order in the column headed "Brand": **METRONIDAMED**

[282] **Schedule 5, entry for Montelukast in the each of the forms: Tablet, chewable, 4 mg (as sodium); and Tablet, chewable, 5 mg (as sodium)**

(a) *insert in alphabetical order in the column headed "Brand":* **APX-MONTELUKAST**

(b) *insert in alphabetical order in the column headed "Brand":* **MONTELUKAST-WGR**

[283] **Schedule 5, entry for Olanzapine in the form Tablet 5 mg**

insert in alphabetical order in the column headed "Brand": **APO-OLANZAPINE**

[284] Schedule 5, entry for Olmesartan with amlodipine in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate)

insert in alphabetical order in the column headed "Brand": **APO-OLMESARTAN/AMLODIPINE 40/5**

[285] Schedule 5, entry for Omeprazole in the form Capsule 20 mg

insert in alphabetical order in the column headed "Brand": **OMEPRAZOLE CAPS WGR**

[286] Schedule 5, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg

substitute:

Ondansetron	GRP-15983	Tablet (orally disintegrating) 4 mg	Oral	APX-Ondansetron ODT Ondansetron Mylan ODT Ondansetron ODT-DRLA Ondansetron ODT Lupin Ondansetron ODT Viatris ONDANSETRON ODT-WGR Ondansetron SZ ODT Zotren ODT

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

insert in alphabetical order in the column headed "Brand": **Perindopril Arginine/Amlodipine-WGR 10/10**

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

insert in alphabetical order in the column headed "Brand": **Perindopril Arginine/Amlodipine-WGR 10/5**

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

insert in alphabetical order in the column headed "Brand": **Perindopril Arginine/Amlodipine-WGR 5/10**

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

insert in alphabetical order in the column headed "Brand": **Perindopril Arginine/Amlodipine-WGR 5/5**

[291] Schedule 5, after entry for Rituximab in the form Solution for I.V. infusion 100 mg in 10 mL

insert:

Rivaroxaban	GRP-29154	Tablet 2.5 mg	Oral	Rivaroxaban-Teva Xarelto
Rivaroxaban	GRP-29169	Tablet 10 mg	Oral	iXarola Rivaroxaban-Teva Xarelto
Rivaroxaban	GRP-29173	Tablet 15 mg	Oral	iXarola Rivaroxaban-Teva Xarelto
Rivaroxaban	GRP-29164	Tablet 20 mg	Oral	iXarola Rivaroxaban-Teva Xarelto

[292] Schedule 5, entry for Rizatriptan in the form Tablet (orally disintegrating) 10 mg (as benzoate)

substitute:

Rizatriptan	GRP-17623	Tablet (orally disintegrating) 10 mg (as benzoate)	Oral	RIXALT Rizatriptan ODT APOTEX RIZATRIPTAN ODT-WGR

[293] Schedule 5, entry for Simvastatin in each of the forms: Tablet 80 mg; Tablet 20 mg; Tablet 40 mg; and Tablet 10 mg

insert in alphabetical order in the column headed "Brand": **SIMVASTATIN-WGR**

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

insert:

Tenofovir with emtricitabine	GRP-21638	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg (S19A)	Oral	Emtricitabine and Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets (Laurus Labs, USA)

[295] Schedule 5, omit entry for Tenofovir with emtricitabine in the form Tablet containing tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg

[296] Schedule 5, after entry for Timolol in the form Eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL (S19A)

insert:

Timolol	GRP-28880	Eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL - (Timoptol-LA) (S19A)	Application to the eye	Timoptol-LA 0.5 % (Santen Oy, Finland)

[297] Schedule 5, entry for Valaciclovir

omit from the column headed "Brand": **Valacor 500**

[298] Schedule 5, entry for Varenicline in the form Box containing 11 tablets 0.5 mg (as tartrate) and 14 tablets 1 mg (as tartrate) in the first pack and 28 tablets 1 mg (as tartrate) in the second pack

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

[299] Schedule 5, entry for Zoledronic acid in the form Solution for I.V. infusion 5 mg (as monohydrate) in 100 mL

omit from the column headed "Brand": **Zoledronic Acid SUN**