PB 128 of 2023

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 13)

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 21 December 2023

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

Contents

1 Name

(1) This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 13)*.

(2) This Instrument may also be cited as PB 128 of 2023.

2 Commencement

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

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. *The whole of this instrument*	*1 January 2024*	*1 January 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 2012 (PB 71 of 2012)

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

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

				a	Abacavir/Lamivudine Viatris	AL	MP NP	C4527 C4528		60	5	30	D(100)

[2] Schedule 1, Part 1, entry for Acalabrutinib

substitute:

Acalabrutinib	Capsule 100 mg	Oral	Calquence	AP	MP	C12495 C12500 C14788		56	5	56	
	Tablet 100 mg	Oral	CALQUENCE	AP	MP	C12495 C12500 C14788 C14795 C14800	P12495 P12500 P14788 P14795	56	5	56	
					MP	C12495 C12500 C14788 C14795 C14800	P14800	56	6	56	

[3] Schedule 1, Part 1, entry for Aciclovir in the form Tablet 200 mg

omit:

				a	GenRx Aciclovir	GX	MP NP	C5942		90	5	90	

[4] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Maximum Quantity: See Note 3; Number of Repeats: See Note 3]*

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

					Adalicip	LR	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)

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

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

Adalicip	LR	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655	P11713	2	0	2

				C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				

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

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

	Adalicip	LR	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2

				C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				

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

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

	Adalicip	LR	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673	2	3	2

				C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				

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

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

	Adalicip	LR	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157	P11107 P12155 P12212 P13556 P13612 P14377 P14378	2	4	2

				C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				

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

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

	Adalicip	LR	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867	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	2	5	2

				C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730	P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730				
			MP	C14107 C14136		2	5	2	C(100)

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

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

	Adalicip	LR	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709	P12273	4	2	2	

	C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730

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

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

	Adalicip	LR	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713	P11529 P12272 P12315	4	5	2

				C14730				

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

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

	Adalicip	LR	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336 P13602 P13609	6	0	2

				C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730					

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

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

	Adalicip	LR	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)

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

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

	Adalicip	LR	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189	P11713	2	0	2	

				C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				

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

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

	Adalicip	LR	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2

				C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				

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

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

	Adalicip	LR	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673	2	3	2

				C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				

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

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

	Adalicip	LR	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855	P11107 P12155 P12212 P13556 P13612 P14377 P14378	2	4	2

				C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				

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

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

	Adalicip	LR	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759	P11523 P11524 P11579 P11604 P11606 P11631 P11635 P11704 P11711 P11717 P11718 P11767 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123	2	5	2

				C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730	P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730				
			MP	C14107 C14136		2	5	2	C(100)

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

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

	Adalicip	LR	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098	6	0	2	

							C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730	P12101 P12147 P13602 P13609			

[20] **Schedule 1, Part 1, entry for Amoxicillin in the form Capsule 500 mg (as trihydrate)** ***[Maximum Quantity: 40; Number of Repeats: 0]***

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

	a	Blooms The Chemist Amoxicillin	BG	MP NP		P10402	40 CN10402	0 CN10402	20	

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

omit:

	Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL (s19A)	Oral	Amoxicillin 250mg/ 5 ml Oral Suspension Sugar Free BP (Kent)	RQ	PDP	1	0	1	
					MP NP	1	1	1	

[22] Schedule 1, Part 1, after entry for Benzathine benzylpenicillin in the form Injection containing 1,200,000 units benzathine benzylpenicillin tetrahydrate in 2.3 mL single use pre-filled syringe

insert:

	Powder for injection 1,200,000 units with diluent 5 mL (S19A)	Injection	Benzylpenicillin Benzathine (Brancaster Pharma, UK)	OJ	MP NP PDP	10	0	1	

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

omit:

			Bortezomib-AFT	AE	MP	C11099 C13745	See Note 3	See Note 3	1	D(100)

[24] Schedule 1, Part 1, entry for Cefaclor in the form Powder for oral suspension 250 mg (as monohydrate) per 5 mL, 75 mL

(a) *omit:*

		a	APO-Cefaclor	TX	PDP	1	0	1	

(b) *omit:*

		a	APO-Cefaclor	TX	MP	1	1	1	

[25] Schedule 1, Part 1, entry for Cefaclor in the form Tablet (sustained release) 375 mg (as monohydrate)

(a) *omit:*

		a	APO-Cefaclor CD	TX	PDP	10	0	10	

(b) *omit:*

	a	APO-Cefaclor CD	TX	MP		10	1	10

[26] Schedule 1, Part 1, entry for Cefazolin in the form Powder for injection 2 g (as sodium)

omit:

	a	Cefazolin-AFT	AE	MP NP	C5826 C5867 C5881 C5890	10	0	5

[27] Schedule 1, Part 1, entry for Cefepime in the form Powder for injection 1 g (as hydrochloride)

omit:

	a	Cefepime-AFT	AE	MP NP	C5842	10	0	1

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

omit:

	a	Ceftriaxone-AFT	AE	MP NP	C5830 C5862 C5868	5	0	1

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

omit:

	a	Ceftriaxone-AFT	AE	MP NP	C5826 C5881 C5890	5	0	1

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

(a) *omit:*

	a	APO-Cyproterone	TX	MP	P5532	20 CN5532	5 CN5532	20

(b) *omit:*

	a	GenRx Cyproterone Acetate	GX	MP	P5532	20 CN5532	5 CN5532	20

(c) *omit:*

			a	APO-Cyproterone	TX	MP			100	5	50

(d) *omit:*

			a	GenRx Cyproterone Acetate	GX	MP			100	5	50

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

(a) *omit:*

			a	APO-Cyproterone	TX	MP			50	5	50

(b) *omit:*

			a	GenRx Cyproterone Acetate	GX	MP			50	5	50

[32] Schedule 1, Part 1, entry for Dabigatran etexilate

substitute:

Dabigatran etexilate	Capsule 75 mg (as mesilate)	Oral		Pradaxa	BY	MP NP	C4369 C4381 C4402	P4381	20	0	10
						MP NP	C4369 C4381 C4402	P4369	20	1	10
			a	ARX-Dabigatran	XT	MP NP	C4402		60	0	60
			a	Pradaxa	BY	MP NP	C4369 C4381 C4402	P4402	60	0	60
	Capsule 110 mg (as mesilate)	Oral		Pradaxa	BY	MP NP	C4269 C4369 C4381 C4402 C14308	P4381	20	0	10
						MP NP	C4269 C4369 C4381 C4402	P4369	20	1	10

							C14308				
		a	ARX-Dabigatran	XT	MP NP	C4269 C4402 C14308	P4402	60	0	60
		a	Dabigatran Sandoz	SZ	MP NP	C4269 C4402 C14308	P4402	60	0	60
		a	Pradaxa	BY	MP NP	C4269 C4369 C4381 C4402 C14308	P4402	60	0	60
		a	ARX-Dabigatran	XT	MP NP	C4269 C4402 C14308	P4269	60	5	60
		a	Dabigatran Sandoz	SZ	MP NP	C4269 C4402 C14308	P4269	60	5	60
		a	Pradaxa	BY	MP NP	C4269 C4369 C4381 C4402 C14308	P4269	60	5	60
		a	ARX-Dabigatran	XT	MP NP	C4269 C4402 C14308	P14308	120	5	60
		a	Dabigatran Sandoz	SZ	MP NP	C4269 C4402 C14308	P14308	120	5	60
		a	Pradaxa	BY	MP NP	C4269 C4369 C4381 C4402 C14308	P14308	120	5	60
Capsule 150 mg (as mesilate)	Oral	a	ARX-Dabigatran	XT	MP NP	C4269 C14308	P4269	60	5	60
		a	Dabigatran Sandoz	SZ	MP NP	C4269 C14308	P4269	60	5	60
		a	Pradaxa	BY	MP NP	C4269 C14308	P4269	60	5	60
		a	ARX-Dabigatran	XT	MP NP	C4269 C14308	P14308	120	5	60
		a	Dabigatran Sandoz	SZ	MP NP	C4269 C14308	P14308	120	5	60
		a	Pradaxa	BY	MP NP	C4269 C14308	P14308	120	5	60

[33] Schedule 1, Part 1, entry for Deferasirox in the form Tablet, dispersible, 125 mg

substitute:

	Tablet, dispersible, 125 mg	Oral	a	Deferasirox Juno	JU	MP	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	168	2	28	D(100)
			a	Pharmacor Deferasirox	CR	MP	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	168	2	28	D(100)
			a	Deferasirox Juno	JU	MP	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	168	5	28	D(100)
			a	Pharmacor Deferasirox	CR	MP	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	168	5	28	D(100)

[34] Schedule 1, Part 1, entry for Deferasirox in the form Tablet, dispersible, 250 mg

substitute:

	Tablet, dispersible, 250 mg	Oral	a	Deferasirox Juno	JU	MP	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	168	2	28	D(100)
			a	Pharmacor Deferasirox	CR	MP	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	168	2	28	D(100)

		a	Deferasirox Juno	JU	MP	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	168	5	28	D(100)
		a	Pharmacor Deferasirox	CR	MP	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	168	5	28	D(100)

[35] Schedule 1, Part 1, entry for Deferasirox in the form Tablet, dispersible, 500 mg

substitute:

Tablet, dispersible, 500 mg	Oral	a	Deferasirox Juno	JU	MP	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	168	2	28	D(100)
		a	Pharmacor Deferasirox	CR	MP	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	168	2	28	D(100)
		a	Deferasirox Juno	JU	MP	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	168	5	28	D(100)
		a	Pharmacor Deferasirox	CR	MP	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	168	5	28	D(100)

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

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

	a	Trazent	AF	MP	C10139		56	5	56

[37] Schedule 1, Part 1, entry for Doxycycline in the form Tablet 50 mg (as monohydrate)

omit:

		APO-Doxycycline	TX	MP NP	C4475 C4529 C4539		25	5	25

[38] Schedule 1, Part 1, entry for Doxycycline in the form Tablet 100 mg (as monohydrate)

substitute:

Tablet 100 mg (as monohydrate)	Oral	Doxycycline Sandoz	HX	PDP			7	0	7
				MP NP			7	1	7
				MP NP		P4485	21	0	7
				MP NP		P4514	28	0	7
				MP		P6200	28	5	7

[39] Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate) *[Maximum Quantity: 30; Number of Repeats: 1]*

(a) *omit:*

		Esomeprazole Apotex	TX	MP	C8774 C8775 C8776 C8780 C8827 C11310	P8774 P8775	30	1	30
				NP	C8774 C8775 C8776 C8780 C8827	P8774 P8775	30	1	30

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

		Esomeprazole Viatris	MQ	MP	C8774 C8775 C8776 C8780 C8827 C11310	P8774 P8775	30	1	30

			NP	C8774 C8775 C8776 C8780 C8827	P8774 P8775	30	1	30

[40] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate)** ***[Maximum Quantity: 30; Number of Repeats: 5]***

(a) *omit:*

	Esomeprazole Apotex	TX	MP	C8774 C8775 C8776 C8780 C8827 C11310	P8776 P8780 P8827	30	5	30
			NP	C8774 C8775 C8776 C8780 C8827	P8776 P8780 P8827	30	5	30

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

	Esomeprazole Viatris	MQ	MP	C8774 C8775 C8776 C8780 C8827 C11310	P8776 P8780 P8827	30	5	30
			NP	C8774 C8775 C8776 C8780 C8827	P8776 P8780 P8827	30	5	30

[41] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate)** ***[Maximum Quantity: 60; Number of Repeats: 5]***

(a) *omit:*

	Esomeprazole Apotex	TX	MP	C8774 C8775 C8776 C8780 C8827 C11310	P11310	60	5	30

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

	Esomeprazole Viatris	MQ	MP	C8774 C8775 C8776 C8780 C8827 C11310	P11310	60	5	30

[42] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate)** ***[Maximum Quantity: 30; Number of Repeats: 1]***

(a) *omit:*

Esomeprazole Apotex	TX	MP	C8777 C8778 C8902 C11370	P8902	30	1	30
		NP	C8777 C8778 C8902	P8902	30	1	30

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

Esomeprazole Viatris	MQ	MP	C8777 C8778 C8902 C11370	P8902	30	1	30
		NP	C8777 C8778 C8902	P8902	30	1	30

[43] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate)** ***[Maximum Quantity: 30; Number of Repeats: 5]***

(a) *omit:*

Esomeprazole Apotex	TX	MP	C8777 C8778 C8902 C11370	P8777 P8778	30	5	30
		NP	C8777 C8778 C8902	P8777 P8778	30	5	30

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

Esomeprazole Viatris	MQ	MP	C8777 C8778 C8902 C11370	P8777 P8778	30	5	30
		NP	C8777 C8778 C8902	P8777 P8778	30	5	30

[44] **Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate)** ***[Maximum Quantity: 60; Number of Repeats: 5]***

(a) *omit:*

		Esomeprazole Apotex	TX	MP	C8777 C8778 C8902 C11370	P11370	60	5	30

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

		Esomeprazole Viatris	MQ	MP	C8777 C8778 C8902 C11370	P11370	60	5	30

[45] Schedule 1, Part 1, entry for Ferric derisomaltose in each of the forms: Injection 500 mg (iron) in 5 mL; and Injection 1000 mg (iron) in 10 mL

omit from the column headed "Responsible Person": **PF** *substitute:* **FK**

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

omit:

	a	APO-Flucloxacillin	TX	MP NP MW	C5414		24	0	24
				PDP	C5298		24	0	24

[47] Schedule 1, Part 1, entry for Flucloxacillin in the form Capsule 500 mg (as sodium monohydrate)

(a) *omit:*

	a	APO-Flucloxacillin	TX	MP	C5414 C6169	P5414	24	0	24
				NP MW	C5414		24	0	24
				PDP	C5298		24	0	24

(b) *omit:*

	a	APO-Flucloxacillin	TX	MP	C5414 C6169	P6169	48	1	24

[48] Schedule 1, Part 1, entry for Furosemide in the form Tablet 20 mg

(a) *omit:*

	a	Urex-M	RW	MP NP			100	1	50

(b) *omit:*

		a	Urex-M	RW	MP NP		P14238	200	1	50

[49] Schedule 1, Part 1, entry for Furosemide in the form Tablet 40 mg

(a) *omit:*

			Urex	RW	MP NP			100	1	100

(b) *omit:*

			Urex	RW	MP NP		P14238	200	1	100

[50] Schedule 1, Part 1, entry for Gabapentin in each of the forms: Capsule 100 mg; Capsule 300 mg; and Capsule 400 mg

omit:

		a	Gabapentin APOTEX	TY	MP NP	C4928		100	5	100

[51] Schedule 1, Part 1, entry for Glimepiride in the form Tablet 3 mg

omit:

		a	Amaryl	SW	MP NP			30	5	30

[52] Schedule 1, Part 1, omit entry for Hydralazine

[53] Schedule 1, Part 1, entry for Hydromorphone in the form Oral solution containing hydromorphone hydrochloride 1 mg per mL, 1 mL

substitute:

	Oral solution containing hydromorphone hydrochloride 1 mg per mL, 1 mL	Oral	Hikma	LM	PDP	C10859		473	0	473
					MP NP	C10764 C10770 C10777 C11697	P10764 P10770 P10777	473	0	473
					MP NP	C10764 C10770 C10777 C11697	P11697	473	1	473

[54] Schedule 1, Part 1, after entry for Hydromorphone in the form Oral solution containing hydromorphone hydrochloride 1 mg per mL, 1 mL

insert:

	Oral solution containing hydromorphone hydrochloride 1mg per mL, 1mL (S19A)	Oral	Hydromorphone hydrochloride oral solution, USP (Medsurge)	DZ	MP NP	C10764 C10770 C10777 C11697	P10764 P10770 P10777	473	0	473
					PDP	C10859		473	0	473
					MP NP	C10764 C10770 C10777 C11697	P11697	473	1	473

[55] Schedule 1, Part 1, entry for Ibrutinib in the form Capsule 140 mg *[Maximum Quantity: 90; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C14344**

(b) *insert in numerical order in the column headed "Circumstances":* **C14788**

(c) *omit from the column headed "Purposes":* **P14344** *substitute:* **P14788**

[56] Schedule 1, Part 1, entry for Ibrutinib in the form Capsule 140 mg *[Maximum Quantity: 120; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C14344**

(b) *insert in numerical order in the column headed "Circumstances":* **C14788**

[57] Schedule 1, Part 1, entry for Ipratropium in each of the forms: Nebuliser solution containing ipratropium bromide 250 micrograms (as monohydrate) in 1 mL single dose units, 30; and Nebuliser solution containing ipratropium bromide 500 micrograms (as monohydrate) in 1 mL single dose units, 30

omit:

	a	APO-Ipratropium	TX	MP NP	C6331 C6341	2	5	1	

[58] Schedule 1, Part 1, entry for Lamotrigine in each of the forms: Tablet 25 mg; Tablet 50 mg; Tablet 100 mg; and Tablet 200 mg

omit:

	a	APO-Lamotrigine	TX	MP NP	C11081	56	5	56	

[59] Schedule 1, Part 1, entry for Levonorgestrel with ethinylestradiol in the form Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets

omit:

			Monofeme 28	FZ	MP NP			4	2	4	

[60] Schedule 1, Part 1, entry for Lumacaftor with ivacaftor

insert as first entry:

	Sachet containing granules, lumacaftor 75 mg and ivacaftor 94 mg	Oral	Orkambi	VR	MP	See Note 3	See Note 3	See Note 3	See Note 3	56	D(100)

[61] Schedule 1, Part 1, entry for Lumacaftor with ivacaftor in each of the forms: Tablet containing lumacaftor 100 mg with ivacaftor 125 mg; and Tablet containing lumacaftor 200 mg with ivacaftor 125 mg

insert in the column headed "Purposes": **See Note 3**

[62] Schedule 1, Part 1, entry for Metformin in the form Tablet (extended release) containing metformin hydrochloride 500 mg

omit:

		a	Metformin XR 500 APOTEX	GX	MP NP			120	5	120	

[63] Schedule 1, Part 1, entry for Metformin in the form Tablet containing metformin hydrochloride 500 mg

omit:

		a	APO-Metformin 500	TX	MP NP			100	5	100	

[64] Schedule 1, Part 1, entry for Metformin in the form Tablet containing metformin hydrochloride 850 mg

omit:

		a	APO-Metformin 850	TX	MP NP			60	5	60	

[65] Schedule 1, Part 1, entry for Metformin in the form Tablet containing metformin hydrochloride 1 g

omit:

			a	APO-Metformin 1000	TX	MP NP			90	5	90

[66] Schedule 1, Part 1, entry for Metoclopramide in the form Injection containing 10 mg metoclopramide hydrochloride (as monohydrate) in 2 mL

substitute:

Metoclopramide	Injection containing 10 mg metoclopramide hydrochloride (as monohydrate) in 2 mL	Injection	a	Maxolon	IL	MP NP MW PDP			10	0	10
			a	METOCLOPRAMIDE INJECTION BP	WZ	MP NP MW PDP			10	0	10
			a	Maxolon	IL	MP NP		P6084	40 CN6084	2 CN6084	10
			a	METOCLOPRAMIDE INJECTION BP	WZ	MP NP		P6084	40 CN6084	2 CN6084	10

[67] Schedule 1, Part 1, entry for Mirtazapine in the form Tablet 15 mg

omit:

			a	APO-Mirtazapine	TX	MP NP	C5650		30	5	30

[68] Schedule 1, Part 1, entry for Mirtazapine in the form Tablet 30 mg

omit:

			a	APO-Mirtazapine	TX	MP NP	C5650		30	5	30

[69] Schedule 1, Part 1, entry for Mirtazapine in the form Tablet 45 mg

omit:

			a	APO-Mirtazapine	TX	MP NP	C5650		30	5	30

[70] Schedule 1, Part 1, entry for Moclobemide in each of the forms: Tablet 150 mg; and Tablet 300 mg

omit:

			a	APO-Moclobemide	TX	MP NP	C5650	60	5	60

[71] Schedule 1, Part 1, entry for Obinutuzumab

insert in numerical order in the column headed "Circumstances": **C14764**

[72] Schedule 1, Part 1, entry for Olanzapine in the form Tablet 5 mg (orally disintegrating)

omit:

				Olanzapine ODT generichealth 5	GQ	MP NP	C5856 C5869	28	5	28

[73] Schedule 1, Part 1, entry for Olaparib

substitute:

Olaparib	Tablet 100 mg	Oral	Lynparza	AP	MP	C12590 C12598 C14741 C14742 C14743 C14760 C14761 C14778	P12590 P14741 P14743 P14761	112	2	56
					MP	C12590 C12598 C14741 C14742 C14743 C14760 C14761 C14778	P12598 P14742 P14760 P14778	112	5	56
	Tablet 150 mg	Oral	Lynparza	AP	MP	C12590 C12598 C14741 C14742 C14743 C14760 C14761 C14778	P12590 P14741 P14743 P14761	112	2	56
					MP	C12590 C12598 C14741 C14742 C14743 C14760 C14761 C14778	P12598 P14742 P14760 P14778	112	5	56

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

(a) *omit:*

			APO-Ondansetron ODT	TX	MP NP	C5618 C10498	P5618	4	0	4	
					MP	C5743		4	0	4	C(100)

(b) *omit:*

			APO-Ondansetron ODT	TX	MP NP	C5618 C10498	P10498	10	1	10	

[75] Schedule 1, Part 1, entry for Ondansetron in the form Tablet 4 mg (as hydrochloride dihydrate)

(a) *omit:*

		a	Ondansetron APOTEX	GX	MP NP	C4118 C10498	P4118	4	0	4	
					MP	C5778		4	0	4	C(100)

(b) *omit:*

		a	Ondansetron APOTEX	GX	MP NP	C4118 C10498	P10498	10	1	10	

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

(a) *omit:*

			APO-Ondansetron ODT	TX	MP NP	C5618 C10498	P5618	4	0	4	
					MP	C5743		4	0	4	C(100)

(b) *omit:*

			APO-Ondansetron ODT	TX	MP NP	C5618 C10498	P10498	10	1	10	

[77] Schedule 1, Part 1, entry for Ondansetron in the form Tablet 8 mg (as hydrochloride dihydrate)

(a) *omit:*

		a	Ondansetron	GX	MP NP	C4118 C10498	P4118	4	0	4	

					APOTEX							
							MP	C5778		4	0	4	C(100)

(b) *omit:*

				a	Ondansetron APOTEX	GX	MP NP	C4118 C10498	P10498	10	1	10	

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

(a) *omit from the column headed "Circumstances":* **C10687**

(b) *omit from the column headed "Circumstances":* **C10695**

(c) *insert in numerical order in the column headed "Circumstances":* **C14770 C14786**

[79] Schedule 1, Part 1, entry for Pirfenidone in the form Tablet 267 mg

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

				a	Pirfenidet	AF	MP	C13378 C13380 C13381		270	5	90	

[80] Schedule 1, Part 1, entry for Pirfenidone in the form Tablet 801mg

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

				a	Pirfenidet	AF	MP	C13380		90	5	90	

[81] Schedule 1, Part 1, entry for Pomalidomide

insert as first entry:

	Capsule 1 mg	Oral		Pomolide	JU	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
						MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
	Capsule 2 mg	Oral		Pomolide	JU	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
						MP	See Note 3	See Note 3	See Note	See Note	21	D(100)

							3	3	

[82] **Schedule 1, Part 1, entry for Pravastatin in each of the forms: Tablet containing pravastatin sodium 10 mg; Tablet containing pravastatin sodium 20 mg; Tablet containing pravastatin sodium 40 mg; and Tablet containing pravastatin sodium 80 mg**

(a) *omit:*

		a	APO-Pravastatin	TX	MP NP		30	5	30

(b) *omit:*

		a	APO-Pravastatin	TX	MP NP	P14238	60	5	30

[83] **Schedule 1, Part 1, entry for Pregabalin in each of the forms: Capsule 25 mg; Capsule 75 mg; Capsule 150 mg; and Capsule 300 mg**

omit:

		a	LYPRALIN	RW	MP NP	C4172	56	5	56

[84] **Schedule 1, Part 1, entry for Raloxifene**

(a) *omit:*

		a	APO-Raloxifene	TX	MP NP	C6314 C14274	P6314	28	5	28

(b) *omit:*

		a	APO-Raloxifene	TX	MP NP	C6314 C14274	P14274	56	5	28

[85] **Schedule 1, Part 1, entry for Ramipril in the form Tablet 1.25 mg *[Maximum Quantity: 30; Number of Repeats: 5]***

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

			Ramipril Viatris	AL	MP NP		30	5	30

[86] **Schedule 1, Part 1, entry for Ramipril in the form Tablet 1.25 mg *[Maximum Quantity: 60; Number of Repeats: 5]***

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

			Ramipril Viatris	AL	MP NP	P14238	60	5	30

[87] Schedule 1, Part 1, entry for Sitagliptin with metformin in the form Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride

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

a	SITAGLIPTIN/METFORMIN 50/500 SUN	RA	MP	C6333 C6334 C6344 C6443 C7507 C7530	56	5	56
			NP	C6333 C6334 C6344 C6443 C7530	56	5	56

[88] Schedule 1, Part 1, entry for Sitagliptin with metformin in the form Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride

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

a	SITAGLIPTIN/METFORMIN 50/850 SUN	RA	MP	C6333 C6334 C6344 C6443 C7507 C7530	56	5	56
			NP	C6333 C6334 C6344 C6443 C7530	56	5	56

[89] Schedule 1, Part 1, entry for Sitagliptin with metformin in the form Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride

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

a	SITAGLIPTIN/METFORMIN 50/1000 SUN	RA	MP	C6333 C6334 C6344 C6443 C7507 C7530	56	5	56
			NP	C6333 C6334 C6344 C6443 C7530	56	5	56

[90] **Schedule 1, Part 1, entry for Sotalol in each of the forms: Tablet containing sotalol hydrochloride 80 mg; and Tablet containing sotalol hydrochloride 160 mg**

omit:

		a	APO-Sotalol	TX	MP NP	C5664	60	5	60

[91] **Schedule 1, Part 1, entry for Temozolomide in the form Capsule 180 mg**

(a) *omit:*

		a	Temodal	MK	MP		5	5	5

(b) *omit:*

		a	Temodal	MK	MP	P4897	15	2	5

[92] **Schedule 1, Part 1, entry for Temozolomide in the form Capsule 250 mg**

omit:

		a	Temodal	MK	MP		5	5	5

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

omit from the column headed "Circumstances" (second instance only): **C14195**

[94] **Schedule 1, Part 1, entry for Triglycerides, medium chain**

omit:

	Oral liquid 225 mL, 15 (K.Quik)	Oral	K.Quik	VF	MP NP	C6147 C6191	2	5	1

[95] **Schedule 1, Part 1, entry for Triglycerides - medium chain, formula**

omit:

	Sachets containing oral powder 16 g, 30 (MCT Pro-Cal)	Oral	MCT Pro-Cal	VF	MP NP	C6136 C6156 C6165 C6173 C6192	4	5	1

[96] **Schedule 1, Part 1, entry for Ustekinumab in the form Injection 90 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 0]***

(a) *insert in numerical order in the column headed "Circumstances":* **C14758 C14787 C14801 C14802 C14806**

(b) *insert in numerical order in the column headed "Purposes":* **P14758 P14787 P14801**

[97] **Schedule 1, Part 1, entry for Ustekinumab in the form Injection 90 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 1]***

(a) *insert in numerical order in the column headed "Circumstances":* **C14758 C14787 C14801 C14802 C14806**

(b) *insert in numerical order in the column headed "Purposes":* **P14802 P14806**

[98] **Schedule 1, Part 1, entry for Varenicline in the form Tablet 1 mg (as tartrate)**

insert in the column headed "Schedule Equivalent" (all instances): **a**

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

omit:

Tablet 1 mg (as tartrate) (s19A)	Oral	APO-Varenicline (Canada)	XT	MP NP	C6885 C7483	P6885	56	2	56
				MP NP	C6885 C7483	P7483	112	0	56

[100] **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**

(a) *omit from the column headed "Circumstances":* **C14325**

(b) *insert in numerical order in the column headed "Circumstances":* **C14776**

[101] **Schedule 1, Part 1, entry for Zanubrutinib**

(a) *omit from the column headed "Circumstances":* **C14344**

(b) *insert in numerical order in the column headed "Circumstances":* **C14788**

[102] **Schedule 1, Part 1, entry for Ziprasidone in each of the forms: Capsule 20 mg (as hydrochloride); Capsule 40 mg (as hydrochloride); Capsule 60 mg (as hydrochloride); and Capsule 80 mg (as hydrochloride)**

omit:

			a	APO-Ziprasidone	TX	MP NP	C4246 C5742		60	5	60

[103] Schedule 1, Part 2, omit entry for Essential amino acids formula with vitamins and minerals

[104] Schedule 1, Part 2, after entry for Filgrastim in the form Injection 480 micrograms in 1.6 mL

insert:

Hydralazine	Tablet containing hydralazine hydrochloride 25 mg	Oral	Alphapress 25	AF	MP NP			200	2	100
	Tablet containing hydralazine hydrochloride 50 mg	Oral	Alphapress 50	AF	MP NP			200	2	100

[105] Schedule 1, Part 2, after entry for Sterculia with frangula bark in the form Granules 620 mg-80 mg per g, 500 g *[Maximum Quantity: 1; Number of Repeats: 3]*

insert:

Triglycerides, medium chain	Oral liquid 225 mL, 15 (K.Quik)	Oral	K.Quik	VF	MP NP	C6147 C6191		2	5	1
Triglycerides - medium chain, formula	Sachets containing oral powder 16 g, 30 (MCT Pro-Cal)	Oral	MCT Pro-Cal	VF	MP NP	C6136 C6156 C6165 C6173 C6192		4	5	1
Varenicline	Tablet 1 mg (as tartrate) (s19A)	Oral	APO-Varenicline (Canada)	XT	MP NP	C6885 C7483	P6885	56	2	56
					MP NP	C6885 C7483	P7483	112	0	56

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

(a) *insert in the column headed "Purposes Code" for the entry for Circumstances Code "C12495":* **P12495**

(b) *insert in the column headed "Purposes Code" for the entry for Circumstances Code "C12500":* **P12500**

(c) *omit:*

	C14344			Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Treatment of relapsed/refractory disease The condition must have relapsed or be refractory to at least one prior therapy; AND The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on	Compliance with Authority Required procedures

				CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication. Patient must not be undergoing retreatment with this drug where prior, active treatment of CLL/SLL with this same drug was unable to prevent disease progression; AND Patient must be undergoing treatment through this treatment phase listing for the first time; OR Patient must be undergoing treatment through this treatment phase listing on a subsequent occasion, with disease progression being absent.	

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

	C14788	P14788		Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Treatment of relapsed/refractory disease The condition must have relapsed or be refractory to at least one prior therapy; 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 the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication. Patient must not be undergoing retreatment (second/subsequent treatment course) with this drug where prior treatment of CLL/SLL with this same drug was unable to prevent disease progression; AND Patient must be undergoing treatment through this treatment phase listing for the first time (initial treatment); OR Patient must be undergoing continuing treatment through this treatment phase listing, with disease progression being absent.	Compliance with Authority Required procedures
	C14795	P14795		Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) First line drug treatment of this indication - as monotherapy The condition must be untreated with acalabrutinib 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 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 the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication. Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug; OR Patient must be undergoing continuing treatment with this drug - the condition has not progressed whilst the patient has actively been on this drug.	Compliance with Authority Required procedures
	C14800	P14800		Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) First line drug treatment of this indication - in combination with obinutuzumab The condition must be untreated with acalabrutinib 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 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 initiated as a monotherapy for 1 Cycle with treatment in combination with obinutuzumab from Cycle 2 to 7 (refer to Product Information for timing of obinutuzumab and acalabrutinib doses) after which treatment must be monotherapy. Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug; OR	Compliance with Authority Required procedures

				Patient must be undergoing continuing treatment with this drug - the condition has not progressed whilst the patient has actively been on this drug.	

[107] Schedule 4, Part 1, entry for Ibrutinib

(a) *omit:*

	C14344	P14344		Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Treatment of relapsed/refractory disease The condition must have relapsed or be refractory to at least one prior therapy; 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 the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication. Patient must not be undergoing retreatment with this drug where prior, active treatment of CLL/SLL with this same drug was unable to prevent disease progression; AND Patient must be undergoing treatment through this treatment phase listing for the first time; OR Patient must be undergoing treatment through this treatment phase listing on a subsequent occasion, with disease progression being absent.	Compliance with Authority Required procedures

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

	C14788	P14788		Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Treatment of relapsed/refractory disease The condition must have relapsed or be refractory to at least one prior therapy; 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 the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication. Patient must not be undergoing retreatment (second/subsequent treatment course) with this drug where prior treatment of CLL/SLL with this same drug was unable to prevent disease progression; AND Patient must be undergoing treatment through this treatment phase listing for the first time (initial treatment); OR Patient must be undergoing continuing treatment through this treatment phase listing, with disease progression being absent.	Compliance with Authority Required procedures

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

insert in numerical order after existing text:

	C14764			Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) For combination use with acalabrutinib from treatment cycles 2 to 7 inclusive in first-line therapy The condition must be untreated; AND The treatment must be in combination with PBS-subsidised acalabrutinib (refer to Product Information for timing of obinutuzumab and acalabrutinib doses).	Compliance with Authority Required procedures - Streamlined Authority Code 14764

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

(a) *omit:*

	C10913	P10913		High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer Continuing treatment - first line treatment Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND The treatment must not exceed a total of 24 months of combined non-PBS-subsidised and PBS-subsidised treatment for patients who are in complete response.	Compliance with Authority Required procedures
	C10937	P10937		High grade epithelial ovarian, fallopian tube or primary peritoneal cancer Continuing treatment - second line treatment Patient must have previously received PBS-subsidised treatment with this drug as a second line therapy for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must be maintenance therapy; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.	Compliance with Authority Required procedures - Streamlined Authority Code 10937
	C10958	P10958		High grade epithelial ovarian, fallopian tube or primary peritoneal cancer Initial treatment - second line treatment The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation; AND The condition must be platinum sensitive; AND Patient must have received at least two previous platinum-containing regimens; AND Patient must have relapsed following a previous platinum-containing regimen; AND Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must be maintenance therapy; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition. Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen. A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines. Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.	Compliance with Authority Required procedures

(b) *omit:*

	C13226	P13226		High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer Initial treatment - first line treatment The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation; AND	Compliance with Authority Required procedures

				Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition. Patient must be undergoing treatment with this drug class for the first time; OR Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal. A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines. Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.	

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

	C14741	P14741		High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer Initial first-line maintenance therapy (BRCA1/2 gene mutation) The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the BRCA1/2 gene(s) - this has been confirmed by a validated test; AND Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition. Patient must be undergoing treatment with this drug class for the first time; OR Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal. A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines. Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.	Compliance with Authority Required procedures
	C14742	P14742		High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer Continuation of first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND The treatment must not exceed a total of 24 months of combined non-PBS-subsidised and PBS-subsidised treatment for patients who are in complete response.	Compliance with Authority Required procedures
	C14743	P14743		High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer Initial first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) The condition must be associated with homologous recombination deficiency (HRD) positive status defined by genomic instability, which has been confirmed by a validated test; AND The condition must not be associated with pathogenic variants (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the BRCA1/2 genes - this has been confirmed by a validated test; AND Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; OR The condition must have both: (i) been in a partial/complete response to the immediately preceding platinum-based	Compliance with Authority Required procedures

				chemotherapy regimen prior to having commenced non-PBS-subsidised treatment with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition. A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines. Evidence of homologous recombination deficiency (genomic instability) must be derived through a test that has been validated against the Myriad MyChoice HRD assay, which uses a score of 42 or greater as the threshold for HRD (genomic instability) positivity. Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above.	
	C14760	P14760		High grade epithelial ovarian, fallopian tube or primary peritoneal cancer Continuation of subsequent-line maintenance therapy (BRCA1/2 gene mutation) The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial subsequent-line maintenance therapy (BRCA1/2 gene mutation); AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.	Compliance with Authority Required procedures - Streamlined Authority Code 14760
	C14761	P14761		High grade epithelial ovarian, fallopian tube or primary peritoneal cancer Initial subsequent-line maintenance therapy (BRCA1/2 gene mutation) The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the BRCA1/2 gene(s) - this has been confirmed by a validated test; AND The condition must be platinum sensitive; AND Patient must have received at least two previous platinum-containing regimens; AND Patient must have relapsed following a previous platinum-containing regimen; AND Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition. Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen. A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines. Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.	Compliance with Authority Required procedures
	C14778	P14778		High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer Continuation of first-line maintenance therapy (BRCA1/2 gene mutation) The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial first-line maintenance therapy (BRCA1/2 gene mutation); AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND The treatment must not exceed a total of 24 months of combined non-PBS-subsidised and PBS-subsidised treatment for patients who are in complete response.	Compliance with Authority Required procedures

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

(a) *omit:*

	C10687			Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma Initial treatment - 3 weekly treatment regimen The treatment must be adjuvant to complete surgical resection; AND Patient must have a WHO performance status of 1 or less; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have received prior PBS-subsidised treatment for this condition; AND The treatment must commence within 12 weeks of complete resection; AND Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.	Compliance with Authority Required procedures

(b) *omit:*

	C10695			Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma Continuing treatment - 3 weekly treatment regimen Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection; AND Patient must not have experienced disease recurrence; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.	Compliance with Authority Required procedures

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

	C14770			Stage IIIB, Stage IIIC or Stage IIID malignant melanoma Initial treatment - 3 weekly treatment regimen The treatment must be in addition to complete surgical resection; AND Patient must have a WHO performance status of 1 or less; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have received prior PBS-subsidised treatment for this condition; AND The treatment must commence within 12 weeks of complete resection; AND Patient must not have received more than 12 months of therapy (irrespective of whether therapy has been partly PBS-subsidised/non-PBS-subsidised).	Compliance with Authority Required procedures
	C14786			Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma Continuing treatment - 3 weekly treatment regimen Patient must be undergoing continuing PBS-subsidised treatment commenced through an 'Initial treatment' listing. Patient must not have experienced disease recurrence; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have received more than 12 months of therapy (irrespective of whether therapy has been partly PBS-subsidised/non-PBS-subsidised).	Compliance with Authority Required procedures

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

insert in numerical order after existing text:

	C14758	P14758		Complex refractory Fistulising Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in 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)]. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted between 8 and 16 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. Applications for authorisation must be made in writing and must include: (1) two completed authority prescription forms; 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 the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and (ii) details of prior biological medicine treatment including details of date and duration of treatment. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats. The most recent fistula assessment must be no more than 4 weeks old at the time of application. A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.	Compliance with Written Authority Required procedures
	C14787	P14787		Complex refractory Fistulising Crohn disease Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including	Compliance with Written Authority Required procedures

				histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have an externally draining enterocutaneous or rectovaginal fistula. 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)]. Applications for authorisation must be made in writing and must include: (1) two completed authority prescription forms; 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 a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats. 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. A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.	
	C14801	P14801		Complex refractory Fistulising Crohn disease Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) 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 of less 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
	C14802	P14802		Complex refractory Fistulising Crohn disease Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have had prior to commencing non-PBS-subsidised treatment: (1) confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; (2) an externally draining enterocutaneous or rectovaginal fistula; AND	Compliance with Written Authority Required procedures

				Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 January 2024; AND Patient must be receiving treatment with this drug for this condition at the time of application; AND Patient must have demonstrated an adequate response to treatment with this drug for this condition if received at least 12 weeks of initial non-PBS-subsidised therapy. 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) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes: (i) the completed baseline Fistula Assessment Form prior to initiating treatment including the date of assessment; (ii) the completed current Fistula Assessment Form including the date of assessment demonstrating the patient's adequate response to treatment if the patient has received at least 12 weeks of treatment. An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks. No repeats will be authorised for patients transitioning from non-PBS-subsidised to PBS-subsidised treatment who have only received the first infusion of ustekinumab. The most recent fistula assessment must be no more than 1 month old at the time of application.	
	C14806	P14806		Complex refractory Fistulising Crohn disease Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to 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 gastroenterology (code 82)]. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. The most recent fistula assessment must be no more than 1 month old at the time of application. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks.	Compliance with Written Authority Required procedures

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

(a) *omit:*

	C14325			Chronic lymphocytic leukaemia (CLL) Dose titration occurring at the start of treatment for relapsed/refractory disease The condition must have relapsed or be refractory to at least one prior therapy; AND The treatment must be the sole PBS-subsidised therapy 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. Patient must not be undergoing retreatment with this drug where prior, active treatment of CLL/SLL with this same drug was unable to prevent disease progression.	Compliance with Authority Required procedures

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

	C14776			Chronic lymphocytic leukaemia (CLL) Dose titration for relapsed/refractory disease The condition must have relapsed or be refractory to at least one prior therapy; AND The treatment must be the sole PBS-subsidised therapy 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. Patient must not be undergoing retreatment with this drug where any of: (i) prior treatment of CLL/SLL with this same drug was unable to prevent disease progression; (ii) 24 months of PBS-subsidised treatment has been administered with this drug for this condition.	Compliance with Authority Required procedures

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

(a) *omit:*

	C14344			Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Treatment of relapsed/refractory disease The condition must have relapsed or be refractory to at least one prior therapy; 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 the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication. Patient must not be undergoing retreatment with this drug where prior, active treatment of CLL/SLL with this same drug was unable to prevent disease progression; AND Patient must be undergoing treatment through this treatment phase listing for the first time; OR Patient must be undergoing treatment through this treatment phase listing on a subsequent occasion, with disease progression being absent.	Compliance with Authority Required procedures

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

	C14788			Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)	Compliance with

				Treatment of relapsed/refractory disease The condition must have relapsed or be refractory to at least one prior therapy; 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 the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication. Patient must not be undergoing retreatment (second/subsequent treatment course) with this drug where prior treatment of CLL/SLL with this same drug was unable to prevent disease progression; AND Patient must be undergoing treatment through this treatment phase listing for the first time (initial treatment); OR Patient must be undergoing continuing treatment through this treatment phase listing, with disease progression being absent.	Authority Required procedures

[114] 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": **Adalicip**

[115] 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": **Adalicip**

[116] Schedule 5, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[GRP-27088]*

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

[117] Schedule 5, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[GRP-27089]*

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

[118] Schedule 5, after entry for Amoxicillin with clavulanic acid in the form Powder for oral suspension containing 400 mg amoxicillin (as trihydrate) with 57 mg clavulanic acid (as potassium clavulanate) per 5 mL, 60 mL *[GRP-28006]*

insert:

Benzathine benzylpenicillin	GRP-28213	Injection containing 1,200,000 units benzathine benzylpenicillin tetrahydrate in 2.3 mL single use pre-filled syringe	Injection	Bicillin L-A
		Powder for injection 1,200,000 units with diluent 5 mL (S19A)	Injection	Benzylpenicillin Benzathine (Brancaster Pharma, UK)

[119] Schedule 5, entry for Doxycycline in the form Tablet 100 mg (as monohydrate) *[GRP-14639]*

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

[120] Schedule 5, entry for Doxycycline in the form Tablet 100 mg (as monohydrate) *[GRP-15555]*

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

[121] **Schedule 5, entry for Doxycycline in the form Tablet 50 mg (as monohydrate)** ***[GRP-15635]***

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

[122] **Schedule 5, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate)** ***[GRP-17061]***

(a) *omit from the column headed "Brand":* **Esomeprazole Apotex**

(b) *insert in alphabetical order in the column headed "Brand":* **Esomeprazole Viatris**

[123] **Schedule 5, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate)** ***[GRP-17188]***

(a) *omit from the column headed "Brand":* **Esomeprazole Apotex**

(b) *insert in alphabetical order in the column headed "Brand":* **Esomeprazole Viatris**

[124] **Schedule 5, entry for Filgrastim in the form Injection 480 micrograms in 0.5 mL single-use pre-filled syringe** ***[GRP-23385]***

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

[125] **Schedule 5, after entry for Glucagon in the form Injection set containing glucagon hydrochloride 1 mg (1 I.U.) and 1 mL solvent in disposable syringe (s19A)** ***[GRP-27816]***

insert:

Hydromorphone	GRP-28212	Oral solution containing hydromorphone hydrochloride 1 mg per mL, 1 mL	Oral	Hikma
		Oral solution containing hydromorphone hydrochloride 1mg per mL, 1mL (S19A)	Oral	Hydromorphone hydrochloride oral solution, USP (Medsurge)

[126] **Schedule 5, entry for Olanzapine in the form Tablet 5 mg (orally disintegrating)** ***[GRP-15797]***

omit from the column headed "Brand": **Olanzapine ODT generichealth 5**

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

omit from the column headed "Brand": **APO-Ondansetron ODT**

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

omit from the column headed "Brand": **APO-Ondansetron ODT**

[129] **Schedule 5, entry for Ramipril in the form Tablet 1.25 mg** ***[GRP-15640]***

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