PB 94 of 2025

National Health (Listing of Pharmaceutical Benefits) Amendment (September Update) Instrument 2025

National Health Act 1953

I, REBECCA RICHARDSON, Assistant Secretary, PBS Listing, Pricing and Policy Branch, Technology Assessment and Access Division, Department of Health, Disability and Ageing, delegate of the Minister for Health and Ageing, make this Instrument under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

Dated 29 August 2025

REBECCA RICHARDSON
Assistant Secretary
PBS Listing, Pricing and Policy Branch
Technology Assessment and Access Division

Contents

1. Name

(1) This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (September Update) Instrument 2025*.

(2) This Instrument may also be cited as PB 94 of 2025.

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 September 2025	1 September 2025

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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, after entry for Abiraterone in the form Tablet containing abiraterone acetate 250 mg *[Brand: Abiraterone-Teva]*

insert:

Abiraterone	Tablet containing abiraterone acetate 250 mg	Oral	ABIRATERONE VIATRIS	AF	MP	C13945		120	2	120

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

insert:

Abiraterone	Tablet containing abiraterone acetate 500 mg	Oral	ABIRATERONE VIATRIS	AF	MP	C13945		60	2	60

[3] Schedule 1, Part 1, entries for Acarbose

omit:

Acarbose	Tablet 50 mg (S19A)	Oral	Acarbose 50 mg tablets (Morningside, UK)	DZ	MP NP			90	5	90
Acarbose	Tablet 50 mg (S19A)	Oral	Acarbose 50 mg tablets (Morningside, UK)	DZ	MP NP		P14238	180	5	90

[4] Schedule 1, Part 1, entries for Aciclovir in the form Tablet 200 mg

omit:

Aciclovir	Tablet 200 mg	Oral	Aciclovir APOTEX	TY	MP NP	C5936		50	0	50

[5] Schedule 1, Part 1, entries for Adalimumab

substitute:

Adalimumab	Injection 20 mg in 0.2 mL pre-filled syringe	Injection	Humira	VE	MP	C11713 C15473	P11713 P15473	2	0	2

Adalimumab	Injection 20 mg in 0.2 mL pre-filled syringe	Injection	Humira	VE	MP	C12120 C14061 C14063 C14064 C14107 C14136	See Note 3	See Note 3	See Note 3	2	C(100)
Adalimumab	Injection 20 mg in 0.2 mL pre-filled syringe	Injection	Humira	VE	MP	C16979 C16982 C16994 C17031 C17032 C17077 C17106	P16979 P16982 P16994 P17031 P17032 P17077 P17106	2	3	2	
Adalimumab	Injection 20 mg in 0.2 mL pre-filled syringe	Injection	Humira	VE	MP	C17005 C17042 C17043 C17044 C17045 C17046	P17005 P17042 P17043 P17044 P17045 P17046	2	4	2	
Adalimumab	Injection 20 mg in 0.2 mL pre-filled syringe	Injection	Humira	VE	MP	C15446 C16991 C16993 C16999 C17002 C17003 C17030 C17065 C17104 C17114	P15446 P16991 P16993 P16999 P17002 P17003 P17030 P17065 P17104 P17114	2	5	2	
Adalimumab	Injection 20 mg in 0.2 mL pre-filled syringe	Injection	Humira	VE	MP	C15474 C15489	P15474 P15489	2	6	2	
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection	Abrilada	PF	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection	Abrilada	PF	MP	C12120 C14061 C14063 C14064 C14107 C14136	See Note 3	See Note 3	See Note 3	2	C(100)
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection	Abrilada	PF	MP	C16979 C16982 C16994 C17031 C17032 C17077 C17106	P16979 P16982 P16994 P17031 P17032 P17077 P17106	2	3	2	
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection	Abrilada	PF	MP	C17005 C17042 C17043 C17044 C17045 C17046	P17005 P17042 P17043 P17044 P17045 P17046	2	4	2	
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection	Abrilada	PF	MP	C15445 C15446 C16991 C16993 C16999 C17002 C17003 C17030 C17065 C17104 C17114	P15445 P15446 P16991 P16993 P16999 P17002 P17003 P17030 P17065 P17104 P17114	2	5	2	

Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection	Abrilada	PF	MP	C15474 C15489	P15474 P15489	2	6	2	
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection	Amgevita	XT	MP	C11713 C15473	P11713 P15473	2	0	1	
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection	Amgevita	XT	MP	C12120 C14061 C14063 C14064 C14107 C14136	See Note 3	See Note 3	See Note 3	1	C(100)
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection	Amgevita	XT	MP	C16979 C16982 C16994 C17031 C17032 C17077 C17106	P16979 P16982 P16994 P17031 P17032 P17077 P17106	2	3	1	
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection	Amgevita	XT	MP	C17005 C17042 C17043 C17044 C17045 C17046	P17005 P17042 P17043 P17044 P17045 P17046	2	4	1	
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection	Amgevita	XT	MP	C15445 C15446 C16991 C16993 C16999 C17002 C17003 C17030 C17065 C17104 C17114	P15445 P15446 P16991 P16993 P16999 P17002 P17003 P17030 P17065 P17104 P17114	2	5	1	
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection	Amgevita	XT	MP	C15474 C15489	P15474 P15489	2	6	1	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hadlima	RF	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hadlima	RF	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	RF	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	2	2	2	
Adalimumab	Injection 40 mg in 0.4 mL	Injection	Hadlima	RF	MP	C9064 C9386	P9064 P9386	2	3	2	

	pre-filled pen					C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673 C16414	P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 P16414			
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hadlima	RF	MP	C11107 C12155 C12212 C13556 C13612 C14377 C14378 C17005 C17042 C17043 C17044 C17045 C17046	P11107 P12155 P12212 P13556 P13612 P14377 P14378 P17005 P17042 P17043 P17044 P17045 P17046	2	4	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hadlima	RF	MP	C11523 C11524 C11604 C11606 C11631 C11635 C11704 C11711 C11865 C11867 C11906 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C16991 C16993 C16999 C17002 C17003 C17030 C17065 C17104 C17114	P11523 P11524 P11604 P11606 P11631 P11635 P11704 P11711 P11865 P11867 P11906 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P16991 P16993 P16999 P17002 P17003 P17030 P17065 P17104 P17114	2	5	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hadlima	RF	MP	C15474 C15489	P15474 P15489	2	6	2
Adalimumab	Injection 40 mg in 0.4 mL	Injection	Hadlima	RF	MP	C15788	P15788	4	2	2

	pre-filled pen										
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hadlima	RF	MP	C11529 C15777 C15796	P11529 P15777 P15796	4	5	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hadlima	RF	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C15764 C15765 C15795 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P15764 P15765 P15795 P16979 P16982 P16994 P17031 P17032 P17077 P17106	6	0	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Humira	VE	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Humira	VE	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	Humira	VE	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	2	2	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Humira	VE	MP	C9064 C9386 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14498 C14655 C14662 C14670 C16414	P9064 P9386 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14498 P14655 P14662 P14670 P16414	2	3	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Humira	VE	MP	C11107 C12155 C12212 C13556 C13612 C14377 C14378 C17005 C17042 C17043 C17044 C17045	P11107 P12155 P12212 P13556 P13612 P14377 P14378 P17005 P17042 P17043 P17044 P17045	2	4	2	

						C17046	P17046				
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Humira	VE	MP	C11704 C11711 C11865 C11867 C11906 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14656 C14713 C14730 C15446 C16991 C16993 C16999 C17002 C17003 C17030 C17065 C17104 C17114	P11704 P11711 P11865 P11867 P11906 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14656 P14713 P14730 P15446 P16991 P16993 P16999 P17002 P17003 P17030 P17065 P17104 P17114	2	5	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Humira	VE	MP	C15474 C15489	P15474 P15489	2	6	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Humira	VE	MP	C15788	P15788	4	2	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Humira	VE	MP	C15777 C15796	P15777 P15796	4	5	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Humira	VE	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C15764 C15765 C15795 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P15764 P15765 P15795 P16979 P16982 P16994 P17031 P17032 P17077 P17106	6	0	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hyrimoz	SZ	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	Hyrimoz	SZ	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	2	2	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C9064 C9386 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673 C16414	P9064 P9386 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 P16414	2	3	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C11107 C12155 C12212 C13556 C13612 C14377 C14378 C17005 C17042 C17043 C17044 C17045 C17046	P11107 P12155 P12212 P13556 P13612 P14377 P14378 P17005 P17042 P17043 P17044 P17045 P17046	2	4	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C11523 C11524 C11604 C11606 C11631 C11635 C11704 C11711 C11865 C11867 C11906 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C16991	P11523 P11524 P11604 P11606 P11631 P11635 P11704 P11711 P11865 P11867 P11906 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P16991	2	5	2

						C16993 C16999 C17002 C17003 C17030 C17065 C17104 C17114	P16993 P16999 P17002 P17003 P17030 P17065 P17104 P17114				
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C15474 C15489	P15474 P15489	2	6	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C15788	P15788	4	2	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C11529 C15777 C15796	P11529 P15777 P15796	4	5	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C15764 C15765 C15795 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P15764 P15765 P15795 P16979 P16982 P16994 P17031 P17032 P17077 P17106	6	0	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Yuflyma	EW	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Yuflyma	EW	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	Yuflyma	EW	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	2	2	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Yuflyma	EW	MP	C9064 C9386 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496	P9064 P9386 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496	2	3	2	

						C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673 C16414	P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 P16414				
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Yuflyma	EW	MP	C11107 C12155 C12212 C13556 C13612 C14377 C14378 C17005 C17042 C17043 C17044 C17045 C17046	P11107 P12155 P12212 P13556 P13612 P14377 P14378 P17005 P17042 P17043 P17044 P17045 P17046	2	4		2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Yuflyma	EW	MP	C11523 C11524 C11604 C11606 C11631 C11635 C11704 C11711 C11865 C11867 C11906 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C16991 C16993 C16999 C17002 C17003 C17030 C17065 C17104 C17114	P11523 P11524 P11604 P11606 P11631 P11635 P11704 P11711 P11865 P11867 P11906 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P16991 P16993 P16999 P17002 P17003 P17030 P17065 P17104 P17114	2	5		2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Yuflyma	EW	MP	C15474 C15489	P15474 P15489	2	6		2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Yuflyma	EW	MP	C15788	P15788	4	2		2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Yuflyma	EW	MP	C11529 C15777 C15796	P11529 P15777 P15796	4	5		2

Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Yuflyma	EW	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C15764 C15765 C15795 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P15764 P15765 P15795 P16979 P16982 P16994 P17031 P17032 P17077 P17106	6	0	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hadlima	RF	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hadlima	RF	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	RF	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	2	2	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hadlima	RF	MP	C9064 C9386 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673 C16414	P9064 P9386 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 P16414	2	3	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hadlima	RF	MP	C11107 C12155 C12212 C13556 C13612 C14377 C14378 C17005 C17042 C17043 C17044 C17045 C17046	P11107 P12155 P12212 P13556 P13612 P14377 P14378 P17005 P17042 P17043 P17044 P17045 P17046	2	4	2	

Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hadlima	RF	MP	C11523 C11524 C11604 C11606 C11631 C11635 C11704 C11711 C11865 C11867 C11906 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C16991 C16993 C16999 C17002 C17003 C17030 C17065 C17104 C17114	P11523 P11524 P11604 P11606 P11631 P11635 P11704 P11711 P11865 P11867 P11906 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P16991 P16993 P16999 P17002 P17003 P17030 P17065 P17104 P17114	2	5	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hadlima	RF	MP	C15474 C15489	P15474 P15489	2	6	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hadlima	RF	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	6	0	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Humira	VE	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Humira	VE	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	Humira	VE	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994	2	2	2	

						C17031 C17032 C17077 C17106	P17031 P17032 P17077 P17106			
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Humira	VE	MP	C9064 C9386 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14498 C14655 C14662 C14670 C16414	P9064 P9386 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14498 P14655 P14662 P14670 P16414	2	3	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Humira	VE	MP	C11107 C12155 C12212 C13556 C13612 C14377 C14378 C17005 C17042 C17043 C17044 C17045 C17046	P11107 P12155 P12212 P13556 P13612 P14377 P14378 P17005 P17042 P17043 P17044 P17045 P17046	2	4	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Humira	VE	MP	C11704 C11711 C11865 C11867 C11906 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14656 C14713 C14730 C15446 C16991 C16993 C16999 C17002 C17003 C17030 C17065 C17104 C17114	P11704 P11711 P11865 P11867 P11906 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14656 P14713 P14730 P15446 P16991 P16993 P16999 P17002 P17003 P17030 P17065 P17104 P17114	2	5	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Humira	VE	MP	C15474 C15489	P15474 P15489	2	6	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Humira	VE	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994	6	0	2

						C17031 C17032 C17077 C17106	P17031 P17032 P17077 P17106				
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hyrimoz	SZ	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hyrimoz	SZ	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	Hyrimoz	SZ	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	2	2	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hyrimoz	SZ	MP	C9064 C9386 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673 C16414	P9064 P9386 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 P16414	2	3	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hyrimoz	SZ	MP	C11107 C12155 C12212 C13556 C13612 C14377 C14378 C17005 C17042 C17043 C17044 C17045 C17046	P11107 P12155 P12212 P13556 P13612 P14377 P14378 P17005 P17042 P17043 P17044 P17045 P17046	2	4	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hyrimoz	SZ	MP	C11523 C11524 C11604 C11606 C11631 C11635 C11704 C11711 C11865 C11867 C11906 C12122 C12123 C12148	P11523 P11524 P11604 P11606 P11631 P11635 P11704 P11711 P11865 P11867 P11906 P12122 P12123 P12148	2	5	2	

						C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C16991 C16993 C16999 C17002 C17003 C17030 C17065 C17104 C17114	P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P16991 P16993 P16999 P17002 P17003 P17030 P17065 P17104 P17114				
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hyrimoz	SZ	MP	C15474 C15489	P15474 P15489	2	6	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Hyrimoz	SZ	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	6	0	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Yuflyma	EW	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Yuflyma	EW	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	Yuflyma	EW	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	2	2	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Yuflyma	EW	MP	C9064 C9386 C12174 C12194 C13599 C13650 C13681 C13694	P9064 P9386 P12174 P12194 P13599 P13650 P13681 P13694	2	3	2	

						C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673 C16414	P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 P16414			
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Yuflyma	EW	MP	C11107 C12155 C12212 C13556 C13612 C14377 C14378 C17005 C17042 C17043 C17044 C17045 C17046	P11107 P12155 P12212 P13556 P13612 P14377 P14378 P17005 P17042 P17043 P17044 P17045 P17046	2	4	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Yuflyma	EW	MP	C11523 C11524 C11604 C11606 C11631 C11635 C11704 C11711 C11865 C11867 C11906 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C16991 C16993 C16999 C17002 C17003 C17030 C17065 C17104 C17114	P11523 P11524 P11604 P11606 P11631 P11635 P11704 P11711 P11865 P11867 P11906 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P16991 P16993 P16999 P17002 P17003 P17030 P17065 P17104 P17114	2	5	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Yuflyma	EW	MP	C15474 C15489	P15474 P15489	2	6	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Yuflyma	EW	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979	6	0	2

						C16982 C16994 C17031 C17032 C17077 C17106	P16982 P16994 P17031 P17032 P17077 P17106				
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Abrilada	PF	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Abrilada	PF	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	Abrilada	PF	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	2	2	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Abrilada	PF	MP	C9064 C9386 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673 C16414	P9064 P9386 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 P16414	2	3	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Abrilada	PF	MP	C11107 C12155 C12212 C13556 C13612 C14377 C14378 C17005 C17042 C17043 C17044 C17045 C17046	P11107 P12155 P12212 P13556 P13612 P14377 P14378 P17005 P17042 P17043 P17044 P17045 P17046	2	4	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Abrilada	PF	MP	C11523 C11524 C11604 C11606 C11631 C11635 C11704 C11711 C11865 C11867 C11906 C12122	P11523 P11524 P11604 P11606 P11631 P11635 P11704 P11711 P11865 P11867 P11906 P12122	2	5	2	

						C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C16991 C16993 C16999 C17002 C17003 C17030 C17065 C17104 C17114	P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P16991 P16993 P16999 P17002 P17003 P17030 P17065 P17104 P17114				
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Abrilada	PF	MP	C15474 C15489	P15474 P15489	2	6	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Abrilada	PF	MP	C15788	P15788	4	2	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Abrilada	PF	MP	C11529 C15777 C15796	P11529 P15777 P15796	4	5	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Abrilada	PF	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C15764 C15765 C15795 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P15764 P15765 P15795 P16979 P16982 P16994 P17031 P17032 P17077 P17106	6	0	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Amgevita	XT	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Amgevita	XT	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	Amgevita	XT	MP	C11709 C11759 C12098 C12101 C12147 C13602	P11709 P11759 P12098 P12101 P12147 P13602	2	2	2	

						C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106			
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Amgevita	XT	MP	C9064 C9386 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673 C16414	P9064 P9386 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 P16414	2	3	2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Amgevita	XT	MP	C11107 C12155 C12212 C13556 C13612 C14377 C14378 C17005 C17042 C17043 C17044 C17045 C17046	P11107 P12155 P12212 P13556 P13612 P14377 P14378 P17005 P17042 P17043 P17044 P17045 P17046	2	4	2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Amgevita	XT	MP	C11523 C11524 C11604 C11606 C11631 C11635 C11704 C11711 C11865 C11867 C11906 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C16991 C16993 C16999 C17002 C17003 C17030 C17065	P11523 P11524 P11604 P11606 P11631 P11635 P11704 P11711 P11865 P11867 P11906 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P16991 P16993 P16999 P17002 P17003 P17030 P17065	2	5	2

						C17104 C17114	P17104 P17114				
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Amgevita	XT	MP	C15474 C15489	P15474 P15489	2	6	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Amgevita	XT	MP	C15788	P15788	4	2	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Amgevita	XT	MP	C11529 C15777 C15796	P11529 P15777 P15796	4	5	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Amgevita	XT	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C15764 C15765 C15795 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P15764 P15765 P15795 P16979 P16982 P16994 P17031 P17032 P17077 P17106	6	0	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Hadlima	RF	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Hadlima	RF	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	Hadlima	RF	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	2	2	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Hadlima	RF	MP	C9064 C9386 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670	P9064 P9386 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670	2	3	2	

						C14672 C14673 C16414	P14672 P14673 P16414				
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Hadlima	RF	MP	C11107 C12155 C12212 C13556 C13612 C14377 C14378 C17005 C17042 C17043 C17044 C17045 C17046	P11107 P12155 P12212 P13556 P13612 P14377 P14378 P17005 P17042 P17043 P17044 P17045 P17046	2	4		2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Hadlima	RF	MP	C11523 C11524 C11604 C11606 C11631 C11635 C11704 C11711 C11865 C11867 C11906 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C16991 C16993 C16999 C17002 C17003 C17030 C17065 C17104 C17114	P11523 P11524 P11604 P11606 P11631 P11635 P11704 P11711 P11865 P11867 P11906 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P16991 P16993 P16999 P17002 P17003 P17030 P17065 P17104 P17114	2	5		2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Hadlima	RF	MP	C15474 C15489	P15474 P15489	2	6		2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Hadlima	RF	MP	C15788	P15788	4	2		2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Hadlima	RF	MP	C11529 C15777 C15796	P11529 P15777 P15796	4	5		2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Hadlima	RF	MP	C11709 C11759 C12098 C12101 C12147 C13602	P11709 P11759 P12098 P12101 P12147 P13602	6	0		2

						C13609 C15764 C15765 C15795 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P13609 P15764 P15765 P15795 P16979 P16982 P16994 P17031 P17032 P17077 P17106				
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Hyrimoz	SZ	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	Hyrimoz	SZ	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	2	2	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C9064 C9386 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673 C16414	P9064 P9386 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 P16414	2	3	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C11107 C12155 C12212 C13556 C13612 C14377 C14378 C17005 C17042 C17043 C17044 C17045 C17046	P11107 P12155 P12212 P13556 P13612 P14377 P14378 P17005 P17042 P17043 P17044 P17045 P17046	2	4	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C11523 C11524 C11604 C11606 C11631 C11635	P11523 P11524 P11604 P11606 P11631 P11635	2	5	2	

						C11704 C11711 C11865 C11867 C11906 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C16991 C16993 C16999 C17002 C17003 C17030 C17065 C17104 C17114	P11704 P11711 P11865 P11867 P11906 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P16991 P16993 P16999 P17002 P17003 P17030 P17065 P17104 P17114				
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C15474 C15489	P15474 P15489	2	6	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C15788	P15788	4	2	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C11529 C15777 C15796	P11529 P15777 P15796	4	5	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C15764 C15765 C15795 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P15764 P15765 P15795 P16979 P16982 P16994 P17031 P17032 P17077 P17106	6	0	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Abrilada	PF	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Abrilada	PF	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	Abrilada	PF	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	2	2	2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Abrilada	PF	MP	C9064 C9386 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673 C16414	P9064 P9386 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 P16414	2	3	2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Abrilada	PF	MP	C11107 C12155 C12212 C13556 C13612 C14377 C14378 C17005 C17042 C17043 C17044 C17045 C17046	P11107 P12155 P12212 P13556 P13612 P14377 P14378 P17005 P17042 P17043 P17044 P17045 P17046	2	4	2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Abrilada	PF	MP	C11523 C11524 C11604 C11606 C11631 C11635 C11704 C11711 C11865 C11867 C11906 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C16991	P11523 P11524 P11604 P11606 P11631 P11635 P11704 P11711 P11865 P11867 P11906 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P16991	2	5	2

						C16993 C16999 C17002 C17003 C17030 C17065 C17104 C17114	P16993 P16999 P17002 P17003 P17030 P17065 P17104 P17114				
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Abrilada	PF	MP	C15474 C15489	P15474 P15489	2	6	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Abrilada	PF	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	6	0	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Amgevita	XT	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Amgevita	XT	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	Amgevita	XT	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	2	2	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Amgevita	XT	MP	C9064 C9386 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673 C16414	P9064 P9386 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 P16414	2	3	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Amgevita	XT	MP	C11107 C12155 C12212 C13556	P11107 P12155 P12212 P13556	2	4	2	

						C13612 C14377 C14378 C17005 C17042 C17043 C17044 C17045 C17046	P13612 P14377 P14378 P17005 P17042 P17043 P17044 P17045 P17046				
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Amgevita	XT	MP	C11523 C11524 C11604 C11606 C11631 C11635 C11704 C11711 C11865 C11867 C11906 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C16991 C16993 C16999 C17002 C17003 C17030 C17065 C17104 C17114	P11523 P11524 P11604 P11606 P11631 P11635 P11704 P11711 P11865 P11867 P11906 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P16991 P16993 P16999 P17002 P17003 P17030 P17065 P17104 P17114	2	5	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Amgevita	XT	MP	C15474 C15489	P15474 P15489	2	6	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Amgevita	XT	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	6	0	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Hadlima	RF	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Hadlima	RF	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	Hadlima	RF	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	2	2	2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Hadlima	RF	MP	C9064 C9386 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673 C16414	P9064 P9386 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 P16414	2	3	2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Hadlima	RF	MP	C11107 C12155 C12212 C13556 C13612 C14377 C14378 C17005 C17042 C17043 C17044 C17045 C17046	P11107 P12155 P12212 P13556 P13612 P14377 P14378 P17005 P17042 P17043 P17044 P17045 P17046	2	4	2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Hadlima	RF	MP	C11523 C11524 C11604 C11606 C11631 C11635 C11704 C11711 C11865 C11867 C11906 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C16991	P11523 P11524 P11604 P11606 P11631 P11635 P11704 P11711 P11865 P11867 P11906 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P16991	2	5	2

						C16993 C16999 C17002 C17003 C17030 C17065 C17104 C17114	P16993 P16999 P17002 P17003 P17030 P17065 P17104 P17114				
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Hadlima	RF	MP	C15474 C15489	P15474 P15489	2	6	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Hadlima	RF	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	6	0	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Hyrimoz	SZ	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Hyrimoz	SZ	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	Hyrimoz	SZ	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	2	2	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Hyrimoz	SZ	MP	C9064 C9386 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673 C16414	P9064 P9386 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 P16414	2	3	2	
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Hyrimoz	SZ	MP	C11107 C12155 C12212 C13556	P11107 P12155 P12212 P13556	2	4	2	

						C13612 C14377 C14378 C17005 C17042 C17043 C17044 C17045 C17046	P13612 P14377 P14378 P17005 P17042 P17043 P17044 P17045 P17046				
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Hyrimoz	SZ	MP	C11523 C11524 C11604 C11606 C11631 C11635 C11704 C11711 C11865 C11867 C11906 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C16991 C16993 C16999 C17002 C17003 C17030 C17065 C17104 C17114	P11523 P11524 P11604 P11606 P11631 P11635 P11704 P11711 P11865 P11867 P11906 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P16991 P16993 P16999 P17002 P17003 P17030 P17065 P17104 P17114	2	5		2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Hyrimoz	SZ	MP	C15474 C15489	P15474 P15489	2	6		2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Hyrimoz	SZ	MP	C11709 C11759 C12098 C12101 C12147 C13602 C13609 C16979 C16982 C16994 C17031 C17032 C17077 C17106	P11709 P11759 P12098 P12101 P12147 P13602 P13609 P16979 P16982 P16994 P17031 P17032 P17077 P17106	6	0		2
Adalimumab	Injection 80 mg in 0.8 mL pre-filled pen	Injection	Humira	VE	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	Humira	VE	MP	C15788	P15788	2	2		1

Adalimumab	Injection 80 mg in 0.8 mL pre-filled pen	Injection	Humira	VE	MP	C15777 C15796	P15777 P15796	2	5	1
Adalimumab	Injection 80 mg in 0.8 mL pre-filled pen	Injection	Humira	VE	MP	C11759 C11762 C11763 C12152 C12229 C15764 C15765 C15795 C16979 C16994 C17031 C17032 C17077 C17106	P11759 P11762 P11763 P12152 P12229 P15764 P15765 P15795 P16979 P16994 P17031 P17032 P17077 P17106	3	0	1
Adalimumab	Injection 80 mg in 0.8 mL pre-filled pen	Injection	Hyrimoz	SZ	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	Hyrimoz	SZ	MP	C15788	P15788	2	2	1
Adalimumab	Injection 80 mg in 0.8 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C11529 C15777 C15796	P11529 P15777 P15796	2	5	1
Adalimumab	Injection 80 mg in 0.8 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C11759 C11762 C11763 C12152 C12229 C15764 C15765 C15795 C16979 C16994 C17031 C17032 C17077 C17106	P11759 P11762 P11763 P12152 P12229 P15764 P15765 P15795 P16979 P16994 P17031 P17032 P17077 P17106	3	0	1
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	C11759 C11762 C11763 C12152 C12229 C15764 C15765 C15795 C16979 C16994 C17031 C17032	P11759 P11762 P11763 P12152 P12229 P15764 P15765 P15795 P16979 P16994 P17031 P17032	3	0	1

						C17077 C17106	P17077 P17106				
Adalimumab	Injection 80 mg in 0.8 mL pre-filled syringe	Injection	Humira	VE	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	Humira	VE	MP	C15788	P15788	2	2		1
Adalimumab	Injection 80 mg in 0.8 mL pre-filled syringe	Injection	Humira	VE	MP	C15777 C15796	P15777 P15796	2	5		1
Adalimumab	Injection 80 mg in 0.8 mL pre-filled syringe	Injection	Humira	VE	MP	C11759 C11762 C11763 C12152 C12229 C15764 C15765 C15795 C16979 C16994 C17031 C17032 C17077 C17106	P11759 P11762 P11763 P12152 P12229 P15764 P15765 P15795 P16979 P16994 P17031 P17032 P17077 P17106	3	0		1
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	C11759 C11762 C11763 C12152 C12229 C15764 C15765 C15795 C16979 C16994 C17031 C17032 C17077 C17106	P11759 P11762 P11763 P12152 P12229 P15764 P15765 P15795 P16979 P16994 P17031 P17032 P17077 P17106	3	0		1

[6] Schedule 1, Part 1, entries for Allopurinol in the form Tablet 300 mg

omit:

Allopurinol	Tablet 300 mg	Oral	Allopurinol APOTEX	GX	MP NP			60	2		60

Allopurinol	Tablet 300 mg	Oral	Allopurinol APOTEX	GX	MP NP		P14238	120	2	60

[7] Schedule 1, Part 1, omit entry for Amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid

[8] Schedule 1, Part 1, omit entry for Amino acid formula with fat, carbohydrate, vitamins, minerals, and trace elements, without methionine and supplemented with docosahexaenoic acid

[9] Schedule 1, Part 1, omit entry for Amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexaenoic acid

[10] Schedule 1, Part 1, entries for Amisulpride in the form Tablet 400 mg

omit:

Amisulpride	Tablet 400 mg	Oral	Amipride 400	RW	MP NP	C4246		60	5	60

[11] Schedule 1, Part 1, entries for Amlodipine in the form Tablet 5 mg (as besilate)

omit:

Amlodipine	Tablet 5 mg (as besilate)	Oral	Blooms the Chemist Amlodipine	IB	MP NP			30	5	30
Amlodipine	Tablet 5 mg (as besilate)	Oral	Blooms the Chemist Amlodipine	IB	MP NP		P14238	60	5	30

[12] Schedule 1, Part 1, entries for Amlodipine in the form Tablet 10 mg (as besilate)

omit:

Amlodipine	Tablet 10 mg (as besilate)	Oral	Blooms the Chemist Amlodipine	IB	MP NP			30	5	30
Amlodipine	Tablet 10 mg (as besilate)	Oral	Blooms the Chemist Amlodipine	IB	MP NP		P14238	60	5	30

[13] Schedule 1, Part 1, entries for Amoxicillin with clavulanic acid in the form Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)

omit:

Amoxicillin with clavulanic acid	Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)	Oral	Amoxycillin/Clavulanic Acid 500/125 APOTEX	TY	MP NP MW	C5832 C5893	P5832 P5893	10	0	10
Amoxicillin with clavulanic acid	Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)	Oral	Amoxycillin/Clavulanic Acid 500/125 APOTEX	TY	PDP	C5833 C5894	P5833 P5894	10	0	10
Amoxicillin with clavulanic acid	Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)	Oral	Amoxycillin/Clavulanic Acid 500/125 APOTEX	TY	MP NP MW	C10405	P10405	20	0	10

[14] Schedule 1, Part 1, entries for Artemether with lumefantrine

omit:

Artemether with lumefantrine	Tablet (dispersible) 20 mg-120 mg	Oral	Riamet 20mg/120mg Dispersible	NV	MP	C6036		18	0	18

[15] Schedule 1, Part 1, after entry for Benzathine benzylpenicillin in the form Injection containing 600,000 units benzathine benzylpenicillin tetrahydrate in 1.17 mL single use pre-filled syringe

insert:

Benzathine benzylpenicillin	Powder for injection 1,200,000 units with diluent 4 mL (S19A)	Injection	Lentocilin S 1200 (Portugal)	NG	MP NP PDP			10	0	10

[16] Schedule 1, Part 1, entries for Benzylpenicillin

omit from the column headed "Responsible Person" (all instances): CS *substitute (all instances):* SZ

[17] Schedule 1, Part 1, entries for Cabozantinib

substitute:

Cabozantinib	Tablet 20 mg	Oral	Cabometyx	IS	MP	C15454 C15774	P15454 P15774	30	2	30
Cabozantinib	Tablet 20 mg	Oral	Cabometyx	IS	MP	C15479 C15775	P15479 P15775	30	5	30
Cabozantinib	Tablet 40 mg	Oral	Cabometyx	IS	MP	C15454 C15774	P15454 P15774	30	2	30
Cabozantinib	Tablet 40 mg	Oral	Cabometyx	IS	MP	C15479 C15775	P15479 P15775	30	5	30
Cabozantinib	Tablet 60 mg	Oral	Cabometyx	IS	MP	C15454 C15774	P15454 P15774	30	2	30
Cabozantinib	Tablet 60 mg	Oral	Cabometyx	IS	MP	C15479 C15775	P15479 P15775	30	5	30

[18] Schedule 1, Part 1, entries for Candesartan with hydrochlorothiazide in the form Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg

omit:

Candesartan with hydrochlorothiazide	Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg	Oral	Blooms the Chemist Candesartan HCTZ 16/12.5	IB	MP NP	C4374	P4374	30	5	30
Candesartan with hydrochlorothiazide	Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg	Oral	Blooms the Chemist Candesartan HCTZ 16/12.5	IB	MP NP	C14255	P14255	60	5	30

[19] Schedule 1, Part 1, entries for Celecoxib in the form Capsule 100 mg

omit:

Celecoxib	Capsule 100 mg	Oral	Blooms the Chemist Celecoxib	IB	MP NP	C4907 C4962		60	3	60

[20] Schedule 1, Part 1, entries for Celecoxib in the form Capsule 100 mg

omit:

Celecoxib	Capsule 100 mg	Oral	Celecoxib APOTEX	TY	MP NP	C4907 C4962		60	3	60

[21] Schedule 1, Part 1, entries for Celecoxib in the form Capsule 200 mg

omit:

Celecoxib	Capsule 200 mg	Oral	Blooms the Chemist Celecoxib	IB	MP NP	C4907 C4962	30	3	30	

[22] Schedule 1, Part 1, entries for Celecoxib in the form Capsule 200 mg

omit:

Celecoxib	Capsule 200 mg	Oral	Celecoxib APOTEX	TY	MP NP	C4907 C4962	30	3	30	

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

omit from the column headed "Responsible Person": JZ *substitute:* XT

[24] Schedule 1, Part 1, after entry for Degarelix in the form Powder for injection 120 mg (as acetate), 2, injection set

insert:

Denosumab	Injection 60 mg in 1 mL pre-filled syringe	Injection	CORORA	GV	MP NP	C6524 C6548	1	0	1	

[25] Schedule 1, Part 1, after entry for Denosumab in the form Injection 60 mg in 1 mL pre-filled syringe *[Brand: Prolia]*

insert:

Denosumab	Injection 120 mg in 1 mL single use pre-filled syringe	Injection	Xgeva	AN	MP NP	C16512 C16514 C16608	1	5	1	

[26] Schedule 1, Part 1, after entry for Denosumab in the form Injection 120 mg in 1 mL single use pre-filled syringe

insert:

Denosumab	Injection 120 mg in 1.7 mL	Injection	GANVADO	GV	MP NP	C16512 C16514 C16608	1	5	1	

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

substitute:

Dupilumab	Injection 200 mg in 1.14 mL single dose pre-filled pen	Injection	Dupixent	SW	MP	C17009 C17016 C17072 C17073 C17113 See Note 3	See Note 3	See Note 3	2	C(100)
Dupilumab	Injection 200 mg in 1.14 mL	Injection	Dupixent	SW	MP	C11374 C11377 P11374 P11377	2	5	2	

	single dose pre-filled pen					C17047 C17076	P17047 P17076				
Dupilumab	Injection 200 mg in 1.14 mL single dose pre-filled syringe	Injection	Dupixent	SW	MP	C15348 C15886 C15924 C17009 C17016 C17072 C17073 C17113	See Note 3	See Note 3	See Note 3	2	C(100)
Dupilumab	Injection 200 mg in 1.14 mL single dose pre-filled syringe	Injection	Dupixent	SW	MP	C11374 C11377 C17047 C17076	P11374 P11377 P17047 P17076	2	5	2	
Dupilumab	Injection 300 mg in 2 mL single dose pre-filled pen	Injection	Dupixent	SW	MP	C17009 C17016 C17072 C17073 C17113	See Note 3	See Note 3	See Note 3	2	C(100)
Dupilumab	Injection 300 mg in 2 mL single dose pre-filled pen	Injection	Dupixent	SW	MP	C11374 C11377 C17047 C17076	P11374 P11377 P17047 P17076	2	5	2	
Dupilumab	Injection 300 mg in 2 mL single dose pre-filled syringe	Injection	Dupixent	SW	MP	C15348 C15424 C15425 C17009 C17016 C17072 C17073 C17113	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 C17047 C17076	P11374 P11377 P17047 P17076	2	5	2	

[28] Schedule 1, Part 1, entry for Etanercept in the form Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL *[Maximum Quantity: 2; Number of Repeats: 3]*

(a) omit from the column headed "Circumstances": C14552

(b) omit from the column headed "Circumstances": C14600

(c) insert in numerical order in the column headed "Circumstances": C17001 C17069

(d) omit from the column headed "Purposes": P14552

(e) omit from the column headed "Purposes": P14600

(f) insert in numerical order in the column headed "Purposes": P17001 P17069

[29] Schedule 1, Part 1, entry for Etanercept in the form Injection 50 mg in 1 mL single use auto-injector, 4 *[Brand: Enbrel; Maximum Quantity: 1; Number of Repeats: 3]*

(a) omit from the column headed "Circumstances": C14552

(b) omit from the column headed "Circumstances": C14600

(c) *insert in numerical order in the column headed "Circumstances":* C17001 C17069

(d) *omit from the column headed "Purposes":* P14552

(e) *omit from the column headed "Purposes":* P14600

(f) *insert in numerical order in the column headed "Purposes":* P17001 P17069

[30] Schedule 1, Part 1, entry for Etanercept in the form Injection 50 mg in 1 mL single use auto-injector, 4 *[Brand: Nepexto; Maximum Quantity: 1; Number of Repeats: 3]*

(a) *omit from the column headed "Circumstances":* C14552

(b) *omit from the column headed "Circumstances":* C14600

(c) *insert in numerical order in the column headed "Circumstances":* C17001 C17069

(d) *omit from the column headed "Purposes":* P14552

(e) *omit from the column headed "Purposes":* P14600

(f) *insert in numerical order in the column headed "Purposes":* P17001 P17069

[31] Schedule 1, Part 1, entry for Etanercept in the form Injections 50 mg in 1 mL single use pre-filled syringes, 4 *[Brand: Enbrel; Maximum Quantity: 1; Number of Repeats: 3]*

(a) *omit from the column headed "Circumstances":* C14552

(b) *omit from the column headed "Circumstances":* C14600

(c) *insert in numerical order in the column headed "Circumstances":* C17001 C17069

(d) *omit from the column headed "Purposes":* P14552

(e) *omit from the column headed "Purposes":* P14600

(f) *insert in numerical order in the column headed "Purposes":* P17001 P17069

[32] Schedule 1, Part 1, entries for Fentanyl

omit:

Fentanyl	Transdermal patch 1.28 mg	Transderm Denpax al	AF	MP NP	C15994 C15996 C16000	P15994 P15996 P16000	5	0	V15994 V15996 V16000	5
Fentanyl	Transdermal patch 1.28 mg	Transderm Denpax al	AF	MP NP	C11696	P11696	10	0	V11696	5

Fentanyl	Transdermal patch 2.063 mg	Transderm al	Fenpatch 12	RW	MP NP	C15994 C15996 C16000	P15994 P15996 P16000	5	0	V15994 V15996 V16000	5
Fentanyl	Transdermal patch 2.063 mg	Transderm al	Fenpatch 12	RW	MP NP	C11696	P11696	10	0	V11696	5

[33] Schedule 1, Part 1, entries for Fentanyl

omit:

Fentanyl	Transdermal patch 2.55 mg	Transderm al	Denpax	AF	MP NP	C15994 C15996 C16000	P15994 P15996 P16000	5	0	V15994 V15996 V16000	5
Fentanyl	Transdermal patch 2.55 mg	Transderm al	Denpax	AF	MP NP	C11696	P11696	10	0	V11696	5
Fentanyl	Transdermal patch 4.125 mg	Transderm al	Fenpatch 25	RW	MP NP	C15994 C15996 C16000	P15994 P15996 P16000	5	0	V15994 V15996 V16000	5
Fentanyl	Transdermal patch 4.125 mg	Transderm al	Fenpatch 25	RW	MP NP	C11696	P11696	10	0	V11696	5

[34] Schedule 1, Part 1, entries for Fentanyl

omit:

Fentanyl	Transdermal patch 5.10 mg	Transderm al	Denpax	AF	MP NP	C15994 C15996 C16000	P15994 P15996 P16000	5	0	V15994 V15996 V16000	5
Fentanyl	Transdermal patch 5.10 mg	Transderm al	Denpax	AF	MP NP	C11696	P11696	10	0	V11696	5
Fentanyl	Transdermal patch 7.65 mg	Transderm al	Denpax	AF	MP NP	C15994 C15996 C16000	P15994 P15996 P16000	5	0	V15994 V15996 V16000	5
Fentanyl	Transdermal patch 7.65 mg	Transderm al	Denpax	AF	MP NP	C11696	P11696	10	0	V11696	5
Fentanyl	Transdermal patch 8.25 mg	Transderm al	Fenpatch 50	RW	MP NP	C15994 C15996 C16000	P15994 P15996 P16000	5	0	V15994 V15996 V16000	5
Fentanyl	Transdermal patch 8.25 mg	Transderm al	Fenpatch 50	RW	MP NP	C11696	P11696	10	0	V11696	5

[35] Schedule 1, Part 1, entries for Fentanyl

omit:

Fentanyl	Transdermal patch 10.20 mg	Transderm al	Denpax	AF	MP NP	C15994 C15996 C16000	P15994 P15996 P16000	5	0	V15994 V15996 V16000	5
Fentanyl	Transdermal patch 10.20 mg	Transderm al	Denpax	AF	MP NP	C11696	P11696	10	0	V11696	5
Fentanyl	Transdermal patch 12.375 mg	Transderm al	Fenpatch 75	RW	MP NP	C15994 C15996 C16000	P15994 P15996 P16000	5	0	V15994 V15996 V16000	5
Fentanyl	Transdermal patch 12.375 mg	Transderm al	Fenpatch 75	RW	MP NP	C11696	P11696	10	0	V11696	5

[36] Schedule 1, Part 1, entries for Fentanyl

omit:

Fentanyl	Transdermal patch 16.5 mg	Transderm al	Fenpatch 100	RW	MP NP	C15994 C15996 C16000	P15994 P15996 P16000	5	0	V15994 V15996 V16000	5
Fentanyl	Transdermal patch 16.5 mg	Transderm al	Fenpatch 100	RW	MP NP	C11696	P11696	10	0	V11696	5

[37] Schedule 1, Part 1, entry for Fosnetupitant with palonosetron

omit from the column headed "Responsible Person": JZ *substitute:* XT

[38] Schedule 1, Part 1, entries for Imatinib in the form Capsule 100 mg (as mesilate)

omit:

Imatinib	Capsule 100 mg (as mesilate)	Oral	Imatinib-APOTEX	TX	MP	C9319 C12525 C12527 C12542 C12543 C13132 C16238 C16249	P9319 P12525 P12527 P12542 P12543 P13132 P16238 P16249	60	2	60
Imatinib	Capsule 100 mg (as mesilate)	Oral	Imatinib-APOTEX	TX	MP	C9204 C9206 C9209 C9238 C9240 C9243 C9274 C9276 C9278 C9296 C12536 C12541	P9204 P9206 P9209 P9238 P9240 P9243 P9274 P9276 P9278 P9296 P12536 P12541	60	5	60

[39] Schedule 1, Part 1, entries for Irbesartan in the form Tablet 300 mg

omit:

Irbesartan	Tablet 300 mg	Oral	Blooms the Chemist Irbesartan	IB	MP NP			30	5	30
Irbesartan	Tablet 300 mg	Oral	Blooms the Chemist Irbesartan	IB	MP NP		P14238	60	5	30

[40] Schedule 1, Part 1, entries for Irbesartan with hydrochlorothiazide in the form Tablet 150 mg-12.5 mg

omit:

Irbesartan with hydrochlorothiazide	Tablet 150 mg-12.5 mg	Oral	Blooms the Chemist Irbesartan HCTZ 150/12.5	IB	MP NP	C4374	P4374	30	5	30
Irbesartan with hydrochlorothiazide	Tablet 150 mg-12.5 mg	Oral	Blooms the Chemist Irbesartan HCTZ 150/12.5	IB	MP NP	C14255	P14255	60	5	30

[41] Schedule 1, Part 1, entries for Irbesartan with hydrochlorothiazide in the form Tablet 300 mg-12.5 mg

omit:

Irbesartan with hydrochlorothiazide	Tablet 300 mg-12.5 mg	Oral	Blooms the Chemist Irbesartan HCTZ 300/12.5	IB	MP NP	C4374	P4374	30	5	30
Irbesartan with hydrochlorothiazide	Tablet 300 mg-12.5 mg	Oral	Blooms the Chemist Irbesartan HCTZ 300/12.5	IB	MP NP	C14255	P14255	60	5	30

[42] Schedule 1, Part 1, entries for Irbesartan with hydrochlorothiazide in the form Tablet 300 mg-25 mg

omit:

Irbesartan with hydrochlorothiazide	Tablet 300 mg-25 mg	Oral	Blooms the Chemist Irbesartan HCTZ 300/25	IB	MP NP	C4374	P4374	30	5	30	
Irbesartan with hydrochlorothiazide	Tablet 300 mg-25 mg	Oral	Blooms the Chemist Irbesartan HCTZ 300/25	IB	MP NP	C14255	P14255	60	5	30	

[43] Schedule 1, Part 1, entries for Iron sucrose

omit from the column headed "Responsible Person" (all instances): VL *substitute (all instances):* CS

[44] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 5 mg

omit from the column headed "Responsible Person": OU *substitute:* RF

[45] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 30 mg

omit from the column headed "Responsible Person": OU *substitute:* RF

[46] Schedule 1, Part 1, after entry for Ivabradine in the form Tablet 7.5 mg (as hydrochloride) *[Brand: Coralan]*

insert:

Ivacaftor	Sachet containing granules 13.4 mg	Oral	Kalydeco	VR	MP	See Note 3	See Note 3	See Note 3	See Note 3	56	D(100)

[47] Schedule 1, Part 1, after entry for Lamivudine in the form Tablet 300 mg *[Brand: Lamivudine Alphapharm]*

insert:

Lamivudine	Tablet 300 mg	Oral	Lamivudine Viatris	AL	MP NP	C4454 C4512	60	5	30	D(100)

[48] Schedule 1, Part 1, after entry for Methylphenidate in the form Capsule containing methylphenidate hydrochloride 10 mg (modified release) *[Brand: Rubifen LA]*

insert:

Methylphenidate	Capsule containing methylphenidate hydrochloride 10 mg	Oral	Methylphenidate Orifarm 10 mg (Sweden)	DZ	MP NP	C16545	30	5	30	

	(modified release) (s19A)								

[49] Schedule 1, Part 1, after entry for Methylphenidate in the form Capsule containing methylphenidate hydrochloride 20 mg (modified release) *[Brand: Rubifen LA]*

insert:

Methylphenidate	Capsule containing methylphenidate hydrochloride 20 mg (modified release) (s19A)	Oral	Methylphenidate Orifarm 20 mg (Sweden)	DZ	MP NP	C16545	30	5	30

[50] Schedule 1, Part 1, after entry for Methylphenidate in the form Capsule containing methylphenidate hydrochloride 30 mg (modified release) *[Brand: Rubifen LA]*

insert:

Methylphenidate	Capsule containing methylphenidate hydrochloride 30 mg (modified release) (s19A)	Oral	Methylphenidate Orifarm 30 mg (Sweden)	DZ	MP NP	C16545	30	5	30

[51] Schedule 1, Part 1, after entry for Methylphenidate in the form Capsule containing methylphenidate hydrochloride 60 mg (modified release) *[Brand: Rubifen LA]*

insert:

Methylphenidate	Capsule containing methylphenidate hydrochloride 60 mg (modified release) (s19A)	Oral	Methylphenidate Orifarm 60 mg (Denmark)	DZ	MP NP	C16545	30	5	30

[52] Schedule 1, Part 1, entry for Metronidazole in the form Oral suspension containing metronidazole benzoate 320 mg per 5 mL, 100 mL

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

[53] Schedule 1, Part 1, entry for Metronidazole in the form Suppositories 500 mg, 10

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

[54] Schedule 1, Part 1, entries for Metronidazole in the form Tablet 400 mg *[Brand: Flagyl]*

omit from the column headed "Responsible Person" (all instances): SW *substitute (all instances):* VJ

[55] Schedule 1, Part 1, entries for Montelukast in the form Tablet, chewable, 5 mg (as sodium)

omit:

Montelukast	Tablet, chewable, 5 mg (as sodium)	Oral	Montelukast Mylan	AF	MP NP	C6674 C7781	P6674 P7781	28	5		28
Montelukast	Tablet, chewable, 5 mg (as sodium)	Oral	Montelukast Mylan	AF	MP NP	C15643 C15644	P15643 P15644	56	5		28

[56] Schedule 1, Part 1, entries for Morphine

omit:

Morphine	Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL (S19A)	Oral	Morphini HCl Streuli	DZ	PDP	C10859	P10859	200	0		20
Morphine	Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL (S19A)	Oral	Morphini HCl Streuli	DZ	MP NP	C10764 C10770 C10777	P10764 P10770 P10777	200	0	V10764 V10770 V10777	20
Morphine	Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL (S19A)	Oral	Morphini HCl Streuli	DZ	MP NP	C11697	P11697	400	1	V11697	20
Morphine	Oral solution containing morphine sulfate 2 mg per mL in 100 mL bottle, 1 mL (S19A)	Oral	Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL)	DZ	MP NP	C10764 C10770 C10777	P10764 P10770 P10777	200	0	V10764 V10770 V10777	100
Morphine	Oral solution containing morphine sulfate 2 mg per mL in 100 mL bottle, 1 mL (S19A)	Oral	Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL)	DZ	PDP	C10859	P10859	200	0		100
Morphine	Oral solution containing morphine sulfate 2 mg per mL in 100 mL bottle, 1 mL (S19A)	Oral	Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL)	DZ	MP NP	C11697	P11697	1000	1	V11697	100
Morphine	Oral solution containing	Oral	Morphine Sulfate	DZ	MP	C10764 C10770	P10764 P10770	200	0	V10764 V10770	500

	morphine sulfate 2 mg per mL in 500 mL bottle, 1 mL (S19A)		(Hikma) 10 mg/5 mL (2 mg/mL)		NP	C10777	P10777			V10777	
Morphine	Oral solution containing morphine sulfate 2 mg per mL in 500 mL bottle, 1 mL (S19A)	Oral	Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL)	DZ	PDP	C10859	P10859	200	0		500
Morphine	Oral solution containing morphine sulfate 2 mg per mL in 500 mL bottle, 1 mL (S19A)	Oral	Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL)	DZ	MP NP	C11697	P11697	2000	1	V11697	500

[57] Schedule 1, Part 1, entries for Morphine in the form Tablet containing morphine sulfate pentahydrate 10 mg (controlled release)

omit:

Morphine	Tablet containing morphine sulfate pentahydrate 10 mg (controlled release)	Oral	MORPHINE MR APOTEX	TX	MP NP	C10748 C10752 C10755	P10748 P10752 P10755	28	0	V10748 V10752 V10755	28
Morphine	Tablet containing morphine sulfate pentahydrate 10 mg (controlled release)	Oral	MORPHINE MR APOTEX	TX	MP NP	C11753	P11753	56	0	V11753	28

[58] Schedule 1, Part 1, entries for Morphine in the form Tablet containing morphine sulfate pentahydrate 30 mg (controlled release)

omit:

Morphine	Tablet containing morphine sulfate pentahydrate 30 mg (controlled release)	Oral	MORPHINE MR APOTEX	TX	MP NP	C10748 C10752 C10755	P10748 P10752 P10755	28	0	V10748 V10752 V10755	28
Morphine	Tablet containing morphine sulfate pentahydrate 30 mg (controlled release)	Oral	MORPHINE MR APOTEX	TX	MP NP	C11753	P11753	56	0	V11753	28

[59] Schedule 1, Part 1, entries for Morphine in the form Tablet containing morphine sulfate pentahydrate 60 mg (controlled release)

omit:

Morphine	Tablet containing morphine sulfate pentahydrate 60 mg	Oral	MORPHINE MR APOTEX	TX	MP NP	C10748 C10752 C10755	P10748 P10752 P10755	28	0	V10748 V10752 V10755	28

	(controlled release)										
Morphine	Tablet containing morphine sulfate pentahydrate 60 mg (controlled release)	Oral	MORPHINE MR APOTEX	TX	MP NP	C11753	P11753	56	0	V11753	28

[60] Schedule 1, Part 1, entries for Morphine in the form Tablet containing morphine sulfate pentahydrate 100 mg (controlled release)

omit:

Morphine	Tablet containing morphine sulfate pentahydrate 100 mg (controlled release)	Oral	MORPHINE MR APOTEX	TX	MP NP	C10748 C10752 C10755	P10748 P10752 P10755	28	0	V10748 V10752 V10755	28
Morphine	Tablet containing morphine sulfate pentahydrate 100 mg (controlled release)	Oral	MORPHINE MR APOTEX	TX	MP NP	C11753	P11753	56	0	V11753	28

[61] Schedule 1, Part 1, entries for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg

omit:

Mycophenolic acid	Tablet containing mycophenolate mofetil 500 mg	Oral	MycoCept	RF	MP			150	5		50
Mycophenolic acid	Tablet containing mycophenolate mofetil 500 mg	Oral	MycoCept	RF	MP		P14238	300	5		50

[62] Schedule 1, Part 1, entry for Netupitant with Palonosetron

omit from the column headed "Responsible Person": JZ *substitute:* XT

[63] Schedule 1, Part 1, entries for Olmesartan with amlodipine in the form Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate)

omit:

Olmesartan with amlodipine	Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate)	Oral	Olmesartan/Amlodipine 20/5 APOTEX	TX	MP NP	C4373	P4373	30	5		30

Olmesartan with amlodipine	Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate)	Oral	Olmesartan/Amlodipine 20/5 APOTEX	TX	MP NP	C14257	P14257	60	5		30	

[64] Schedule 1, Part 1, entries for Omeprazole in the form Capsule 20 mg

omit:

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

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

omit:

Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron	TX	MP NP	C4118	P4118	4	0	V4118	4	
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron	TX	MP	C5778	P5778	4	0	V5778	4	C(100)
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron	TX	MP NP	C15193	P15193	10	1		10	

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

omit:

Ondansetron	Tablet 8 mg (as	Oral	APO-Ondansetron	TX	MP	C4118	P4118	4	0	V4118	4	

	hydrochloride dihydrate)				NP							
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron	TX	MP	C5778	P5778	4	0	V5778	4	C(100)
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron	TX	MP NP	C15193	P15193	10	1		10	

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

insert:

Palovarotene	Capsule 1 mg	Oral	Sohonos	IS	MP	C17018	P17018	28	2		28
Palovarotene	Capsule 1 mg	Oral	Sohonos	IS	MP	C17017	P17017	28	5		28
Palovarotene	Capsule 1.5 mg	Oral	Sohonos	IS	MP	C17018	P17018	28	2		28
Palovarotene	Capsule 1.5 mg	Oral	Sohonos	IS	MP	C17017	P17017	28	5		28
Palovarotene	Capsule 2.5 mg	Oral	Sohonos	IS	MP	C17018	P17018	28	2		28
Palovarotene	Capsule 2.5 mg	Oral	Sohonos	IS	MP	C17017	P17017	28	5		28
Palovarotene	Capsule 5 mg	Oral	Sohonos	IS	MP	C17018	P17018	28	2		28
Palovarotene	Capsule 5 mg	Oral	Sohonos	IS	MP	C17017	P17017	28	5		28

[68] Schedule 1, Part 1, entries for Paroxetine

omit:

Paroxetine	Tablet 20 mg (as hydrochloride)	Oral	APO-Paroxetine	TX	MP NP	C4755 C6277 C6636	P4755 P6277 P6636	30	5		30
Paroxetine	Tablet 20 mg (as hydrochloride)	Oral	APO-Paroxetine	TX	MP NP	C15582 C15666 C15722	P15582 P15666 P15722	60	2		30

[69] Schedule 1, Part 1, after entry for Peginterferon alfa-2a in the form Injection 135 micrograms in 0.5 mL single use pre-filled syringe

insert:

Peginterferon	Injection 135 micrograms in	Injection	Pegasys (Ireland)	XO	MP			4	5		4

alfa-2a	0.5 mL single use pre-filled syringe (s19A)				NP					

[70] Schedule 1, Part 1, after entry for Peginterferon alfa-2a in the form Injection 180 micrograms in 0.5 mL single use pre-filled syringe

insert:

Peginterferon alfa-2a	Injection 180 micrograms in 0.5 mL single use pre-filled syringe (s19A)	Injection	Pegasys (Ireland)	XO	MP NP		4	5	4	

[71] Schedule 1, Part 1, entries for Pemetrexed in the form Powder for I.V. infusion 500 mg (as disodium)

omit:

Pemetrexed	Powder for I.V. infusion 500 mg (as disodium)	Injection	Pemetrexed APOTEX	TX	MP		See Note 3	See Note 3	1	D(100)

[72] Schedule 1, Part 1, entries for Perindopril in the form Tablet containing perindopril erbumine 2 mg

omit:

Perindopril	Tablet containing perindopril erbumine 2 mg	Oral	Blooms the Chemist Perindopril	IB	MP NP		30	5	30	
Perindopril	Tablet containing perindopril erbumine 2 mg	Oral	Blooms the Chemist Perindopril	IB	MP NP	P14238	60	5	30	

[73] Schedule 1, Part 1, entries for Perindopril in the form Tablet containing perindopril erbumine 4 mg

omit:

Perindopril	Tablet containing perindopril erbumine 4 mg	Oral	Blooms the Chemist Perindopril	IB	MP NP		30	5	30	
Perindopril	Tablet containing perindopril erbumine 4 mg	Oral	Blooms the Chemist Perindopril	IB	MP NP	P14238	60	5	30	

[74] Schedule 1, Part 1, entries for Perindopril in the form Tablet containing perindopril erbumine 8 mg

omit:

Perindopril	Tablet containing perindopril erbumine 8 mg	Oral	Blooms the Chemist Perindopril	IB	MP NP			30	5	30
Perindopril	Tablet containing perindopril erbumine 8 mg	Oral	Blooms the Chemist Perindopril	IB	MP NP		P14238	60	5	30

[75] Schedule 1, Part 1, entries for Pioglitazone in the form Tablet 15 mg (as hydrochloride)

omit:

Pioglitazone	Tablet 15 mg (as hydrochloride)	Oral	APOTEX-Pioglitazone	TX	MP NP	C15321	P15321	28	5	28
Pioglitazone	Tablet 15 mg (as hydrochloride)	Oral	APOTEX-Pioglitazone	TX	MP NP	C15290	P15290	56	5	28

[76] Schedule 1, Part 1, entries for Pramipexole in the form Tablet (extended release) containing pramipexole dihydrochloride monohydrate 375 micrograms

omit:

Pramipexole	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 375 micrograms	Oral	APO-Pramipexole ER	TX	MP NP	C16536	P16536	30	5	30
Pramipexole	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 375 micrograms	Oral	APO-Pramipexole ER	TX	MP NP	C16540	P16540	60	5	30

[77] Schedule 1, Part 1, entries for Pramipexole in the form Tablet (extended release) containing pramipexole dihydrochloride monohydrate 750 micrograms

omit:

Pramipexole	Tablet (extended release) containing pramipexole	Oral	APO-Pramipexole	TX	MP	C16536	P16536	30	5	30

	dihydrochloride monohydrate 750 micrograms		ER		NP					
Pramipexole	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 750 micrograms	Oral	APO-Pramipexole ER	TX	MP NP	C16540	P16540	60	5	30

[78] Schedule 1, Part 1, entries for Pramipexole in the form Tablet (extended release) containing pramipexole dihydrochloride monohydrate 1.5 mg

omit:

Pramipexole	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 1.5 mg	Oral	APO-Pramipexole ER	TX	MP NP	C16536	P16536	30	5	30
Pramipexole	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 1.5 mg	Oral	APO-Pramipexole ER	TX	MP NP	C16540	P16540	60	5	30

[79] Schedule 1, Part 1, entries for Pramipexole in the form Tablet (extended release) containing pramipexole dihydrochloride monohydrate 2.25 mg

omit:

Pramipexole	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 2.25 mg	Oral	APO-Pramipexole ER	TX	MP NP	C16536	P16536	30	5	30
Pramipexole	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 2.25 mg	Oral	APO-Pramipexole ER	TX	MP NP	C16540	P16540	60	5	30

[80] Schedule 1, Part 1, entries for Pramipexole in the form Tablet (extended release) containing pramipexole dihydrochloride monohydrate 3 mg

omit:

Pramipexole	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 3 mg	Oral	APO-Pramipexole ER	TX	MP NP	C16536	P16536	30	5	30
Pramipexole	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 3 mg	Oral	APO-Pramipexole ER	TX	MP NP	C16540	P16540	60	5	30

[81] Schedule 1, Part 1, entries for Pramipexole in the form Tablet (extended release) containing pramipexole dihydrochloride monohydrate 3.75 mg

omit:

Pramipexole	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 3.75 mg	Oral	APO-Pramipexole ER	TX	MP NP	C16536	P16536	30	5	30
Pramipexole	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 3.75 mg	Oral	APO-Pramipexole ER	TX	MP NP	C16540	P16540	60	5	30

[82] Schedule 1, Part 1, entries for Pramipexole in the form Tablet (extended release) containing pramipexole dihydrochloride monohydrate 4.5 mg

omit:

Pramipexole	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 4.5 mg	Oral	APO-Pramipexole ER	TX	MP NP	C16536	P16536	30	5	30
Pramipexole	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 4.5 mg	Oral	APO-Pramipexole ER	TX	MP NP	C16540	P16540	60	5	30

[83] Schedule 1, Part 1, after entry for Prazosin in the form Capsule 1 mg (as hydrochloride) (S19A) *[Maximum Quantity: 200; Number of Repeats: 5]*

insert:

Prazosin	Capsule 2 mg (as hydrochloride) (S19A)	Oral	Prazosin Hydrochloride Capsules, USP 2 mg (Novitium Pharma, USA)	DZ	MP NP			100	5	100
Prazosin	Capsule 2 mg (as hydrochloride) (S19A)	Oral	Prazosin Hydrochloride Capsules, USP 2 mg (Novitium Pharma, USA)	DZ	MP NP		P14238	200	5	100

[84] Schedule 1, Part 1, entries for Pregabalin in the form Capsule 25 mg

omit:

Pregabalin	Capsule 25 mg	Oral	Blooms The Chemist Pregabalin	IB	MP NP	C4172		56	5	56

[85] Schedule 1, Part 1, entries for Pregabalin in the form Capsule 150 mg

omit:

Pregabalin	Capsule 150 mg	Oral	Blooms The Chemist Pregabalin	IB	MP NP	C4172		56	5	56

[86] Schedule 1, Part 1, entries for Pregabalin in the form Capsule 300 mg

omit:

Pregabalin	Capsule 300 mg	Oral	Blooms The Chemist Pregabalin	IB	MP NP	C4172		56	5	56

[87] Schedule 1, Part 1, after entry for Rituximab in the form Solution for I.V. infusion 500 mg in 50 mL *[Brand: Truxima; Maximum Quantity: See Note 3]*

insert:

Rivaroxaban	Capsule 15 mg	Oral	Relaban	NB	MP NP	C4269	P4269	28	5	28
Rivaroxaban	Capsule 15 mg	Oral	Relaban	NB	MP NP	C14301	P14301	56	5	28
Rivaroxaban	Capsule 20 mg	Oral	Relaban	NB	MP NP	C4099 C4132 C4268 C4269	P4099 P4132 P4268 P4269	28	5	28
Rivaroxaban	Capsule 20 mg	Oral	Relaban	NB	MP NP	C14264 C14300 C14301 C14318	P14264 P14300 P14301 P14318	56	5	28

[88] Schedule 1, Part 1, entries for Rivaroxaban in the form Tablet 15 mg

omit:

Rivaroxaban	Tablet 15 mg	Oral	Relaban	NB	MP NP	C4269	P4269	28	5	28
Rivaroxaban	Tablet 15 mg	Oral	Relaban	NB	MP NP	C14301	P14301	56	5	28

[89] Schedule 1, Part 1, entries for Rivaroxaban in the form Tablet 20 mg

omit:

Rivaroxaban	Tablet 20 mg	Oral	Relaban	NB	MP NP	C4099 C4132 C4268 C4269	P4099 P4132 P4268 P4269	28	5	28
Rivaroxaban	Tablet 20 mg	Oral	Relaban	NB	MP NP	C14264 C14300 C14301 C14318	P14264 P14300 P14301 P14318	56	5	28

[90] Schedule 1, Part 1, entries for Rosuvastatin in the form Tablet 5 mg (as calcium)

omit:

Rosuvastatin	Tablet 5 mg (as calcium)	Oral	Rosuvastatin APOTEX	GX	MP NP			30	5	30
Rosuvastatin	Tablet 5 mg (as calcium)	Oral	Rosuvastatin APOTEX	GX	MP NP		P14238	60	5	30

[91] Schedule 1, Part 1, entries for Roxithromycin in the form Tablet 150 mg

omit:

Roxithromycin	Tablet 150 mg	Oral	APO-Roxithromycin	TX	MP NP PDP		10	0	10
Roxithromycin	Tablet 150 mg	Oral	APO-Roxithromycin	TX	MP NP	P10404	20 CN10404	0 CN10404	10

[92] Schedule 1, Part 1, entries for Roxithromycin in the form Tablet 300 mg

omit:

Roxithromycin	Tablet 300 mg	Oral	APO-Roxithromycin	TX	MP NP PDP		5	0	5
Roxithromycin	Tablet 300 mg	Oral	APO-Roxithromycin	TX	MP NP	P10404	10 CN10404	0 CN10404	5

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

(a) insert in numerical order in the column headed "Circumstances": C17019 C17052 C17053 C17054

(b) insert in numerical order in the column headed "Purposes": P17019 P17052 P17053 P17054

[94] Schedule 1, Part 1, first entry for Ruxolitinib in the form Tablet 10 mg *[Maximum Quantity: 56; Number of Repeats: 5]*

(a) insert in numerical order in the column headed "Circumstances": C17019 C17052 C17053 C17054

(b) insert in numerical order in the column headed "Purposes": P17019 P17052 P17053 P17054

[95] Schedule 1, Part 1, entry for Ruxolitinib in the form Tablet 15 mg *[Maximum Quantity: 56; Number of Repeats: 5]*

(a) insert in numerical order in the column headed "Circumstances": C17019 C17052 C17053 C17054

(b) insert in numerical order in the column headed "Purposes": P17019 P17052 P17053 P17054

[96] Schedule 1, Part 1, entry for Ruxolitinib in the form Tablet 20 mg *[Maximum Quantity: 56; Number of Repeats: 5]*

(a) insert in numerical order in the column headed "Circumstances": C17019 C17052 C17053 C17054

(b) insert in numerical order in the column headed "Purposes": P17019 P17052 P17053 P17054

[97] Schedule 1, Part 1, entry for Secukinumab in the form Injection 150 mg in 1 mL pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 3]*

(a) omit from the column headed "Circumstances": C15799 C15806

(b) omit from the column headed "Circumstances": C15810

(c) insert in numerical order in the column headed "Circumstances": C17025 C17026 C17028

(d) omit from the column headed "Purposes": P15799 P15806

(e) omit from the column headed "Purposes": P15810

(f) insert in numerical order in the column headed "Purposes": P17025 P17026 P17028

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

(a) omit from the column headed "Circumstances": C15768 C15805 C15812

(b) insert in numerical order in the column headed "Circumstances": C16977 C17057 C17058

(c) omit from the column headed "Purposes": P15768 P15805 P15812

(d) insert in numerical order in the column headed "Purposes": P16977 P17057 P17058

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

insert:

Secukinumab	Injection 300 mg in 2 mL pre-filled pen	Injection	Cosentyx	NV	MP	C8831 C9064 C9429	P8831 P9064 P9429	1	2	1
Secukinumab	Injection 300 mg in 2 mL pre-filled pen	Injection	Cosentyx	NV	MP	C15807 C17025 C17026 C17028	P15807 P17025 P17026 P17028	1	3	1
Secukinumab	Injection 300 mg in 2 mL pre-filled pen	Injection	Cosentyx	NV	MP	C6696 C8830 C8892 C9063 C9105 C9431 C14692 C15767	P6696 P8830 P8892 P9063 P9105 P9431 P14692 P15767	1	5	1
Secukinumab	Injection 300 mg in 2 mL pre-filled pen	Injection	Cosentyx	NV	MP	C9069 C9155 C11089 C11096 C11138 C11154 C14430 C14462 C14655 C14662	P9069 P9155 P11089 P11096 P11138 P11154 P14430 P14462 P14655 P14662	4	0	1

	C14670 C16382 P14670 P16382 C16977 C17057 P16977 P17057 C17058 P17058

[100] Schedule 1, Part 1, entries for Sucroferric oxyhydroxide

omit from the column headed "Responsible Person" (all instances): VL *substitute (all instances):* CS

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

(a) omit from the column headed "Circumstances": C16862 C16887

(b) omit from the column headed "Circumstances": C16968 C16969

(c) insert in numerical order in the column headed "Circumstances": C17000 C17080 C17093 C17094

(d) omit from the column headed "Purposes": P16862 P16887

(e) omit from the column headed "Purposes": P16968 P16969

(f) insert in numerical order in the column headed "Purposes": P17000 P17080 P17093 P17094

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

(a) omit from the column headed "Circumstances": C16819

(b) omit from the column headed "Circumstances": C16838 C16857

(c) omit from the column headed "Circumstances": C16901

(d) omit from the column headed "Circumstances": C16938

(e) insert in numerical order in the column headed "Circumstances": C17039 C17067 C17068 C17070 C17071

(f) omit from the column headed "Purposes": P16819

(g) omit from the column headed "Purposes": P16838 P16857

(h) omit from the column headed "Purposes": P16901

(i) omit from the column headed "Purposes": P16938

(j) insert in numerical order in the column headed "Purposes": P17039 P17067 P17068 P17070 P17071

[103] Schedule 1, Part 1, entry for Ustekinumab in the form Injection 45 mg in 0.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 1]*

(a) omit from the column headed "Circumstances": C16862

(b) *omit from the column headed "Circumstances":* C16887

(c) *insert in numerical order in the column headed "Circumstances":* C17080 C17093

(d) *omit from the column headed "Purposes":* P16862

(e) *omit from the column headed "Purposes":* P16887

(f) *insert in numerical order in the column headed "Purposes":* P17080 P17093

[104] Schedule 1, Part 1, entry for Ustekinumab in the form Injection 45 mg in 0.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 2]*

(a) *omit from the column headed "Circumstances":* C16819

(b) *omit from the column headed "Circumstances":* C16838 C16857

(c) *omit from the column headed "Circumstances":* C16901

(d) *omit from the column headed "Circumstances":* C16938

(e) *insert in numerical order in the column headed "Circumstances":* C17039 C17067 C17068 C17070 C17071

(f) *omit from the column headed "Purposes":* P16819

(g) *omit from the column headed "Purposes":* P16838 P16857

(h) *omit from the column headed "Purposes":* P16901

(i) *omit from the column headed "Purposes":* P16938

(j) *insert in numerical order in the column headed "Purposes":* P17039 P17067 P17068 P17070 P17071

[105] 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) *omit from the column headed "Circumstances":* C16862

(b) *omit from the column headed "Circumstances":* C16887

(c) *insert in numerical order in the column headed "Circumstances":* C17080 C17093

(d) *omit from the column headed "Purposes":* P16862

(e) *omit from the column headed "Purposes":* P16887

(f) *insert in numerical order in the column headed "Purposes":* P17080 P17093

[106] 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: 2]*

(a) omit from the column headed "Circumstances": C16819

(b) omit from the column headed "Circumstances": C16838 C16857

(c) omit from the column headed "Circumstances": C16901

(d) omit from the column headed "Circumstances": C16938

(e) insert in numerical order in the column headed "Circumstances": C17039 C17067 C17068 C17070 C17071

(f) omit from the column headed "Purposes": P16819

(g) omit from the column headed "Purposes": P16838 P16857

(h) omit from the column headed "Purposes": P16901

(i) omit from the column headed "Purposes": P16938

(j) insert in numerical order in the column headed "Purposes": P17039 P17067 P17068 P17070 P17071

[107] Schedule 1, Part 1, entries for Valaciclovir

omit:

Valaciclovir	Tablet 500 mg (as hydrochloride)	Oral	Valaciclovir APOTEX	GX	MP NP	C5960	P5960	20	0	10	
Valaciclovir	Tablet 500 mg (as hydrochloride)	Oral	Valaciclovir APOTEX	GX	MP NP MW	C5940	P5940	30	5	30	
Valaciclovir	Tablet 500 mg (as hydrochloride)	Oral	Valaciclovir APOTEX	GX	MP NP	C5961	P5961	30	5	30	
Valaciclovir	Tablet 500 mg (as hydrochloride)	Oral	Valaciclovir APOTEX	GX	MP NP	C5962 C5968	P5962 P5968	42	0	42	
Valaciclovir	Tablet 500 mg (as hydrochloride)	Oral	Valaciclovir APOTEX	GX	MP	C5975 C9267		500	2	100	C(100)

[108] Schedule 1, Part 1, entries for Vinorelbine in the form Solution for I.V. infusion 50 mg (as tartrate) in 5 mL

omit:

Vinorelbine	Solution for I.V. infusion 50 mg (as tartrate) in 5 mL	Injection	Navelbine	FB	MP		See Note 3	See Note 3	1	PB(100)

[109] Schedule 1, Part 2, omit entry for Amino acid formula with vitamins and minerals without lysine and low in tryptophan

[110] Schedule 3, after entry for Responsible Person Code GT

insert:

GV	Amgen Australia Pty Limited	31 051 057 428

[111] Schedule 3

omit:

IB	Apotex Pty Ltd	52 096 916 148

[112] Schedule 3

omit:

JZ	Juniper Biologics Pty Ltd	97 655 479 897

[113] Schedule 3

omit:

OU	Oraderm Pharmaceuticals Pty Ltd	50 612 828 618

[114] Schedule 3, after entry for Responsible Person Code VI

insert:

VJ	VITALION PTY LTD	33 677 876 014

[115] Schedule 3

omit:

VL	Vifor Pharma Pty Limited	87 086 114 043

[116] Schedule 4, Part 1, omit entry for Circumstances Code "C4084"

[117] Schedule 4, Part 1, omit entry for Circumstances Code "C4095"

[118] Schedule 4, Part 1, omit entry for Circumstances Code "C5004"

[119] Schedule 4, Part 1, entry for Circumstances Code "C5533"

omit from the column headed "Listed Drug": Amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid

[120] Schedule 4, Part 1, entry for Circumstances Code "C5534"

omit from the column headed "Listed Drug": Amino acid formula with fat, carbohydrate, vitamins, minerals, and trace elements, without methionine and supplemented with docosahexaenoic acid

[121] Schedule 4, Part 1, omit entry for Circumstances Code "C5554"

[122] Schedule 4, Part 1, omit entry for Circumstances Code "C5569"

[123] Schedule 4, Part 1, entry for Circumstances Code "C5571"

omit from the column headed "Listed Drug": Amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexaenoic acid

[124] Schedule 4, Part 1, omit entry for Circumstances Code "C5600"

[125] Schedule 4, Part 1, omit entry for Circumstances Code "C5653"

[126] Schedule 4, Part 1, omit entry for Circumstances Code "C5795"

[127] Schedule 4, Part 1, omit entry for Circumstances Code "C6036"

[128] Schedule 4, Part 1, omit entry for Circumstances Code "C9603"

[129] Schedule 4, Part 1, omit entry for Circumstances Code "C9689"

[130] Schedule 4, Part 1, omit entry for Circumstances Code "C9690"

[131] Schedule 4, Part 1, omit entry for Circumstances Code "C9691"

[132] Schedule 4, Part 1, omit entry for Circumstances Code "C9692"

[133] Schedule 4, Part 1, omit entry for Circumstances Code "C9693"

[134] **Schedule 4, Part 1, omit entry for Circumstances Code "C9697"**

[135] **Schedule 4, Part 1, omit entry for Circumstances Code "C9715"**

[136] **Schedule 4, Part 1, omit entry for Circumstances Code "C9809"**

[137] **Schedule 4, Part 1, omit entry for Circumstances Code "C9914"**

[138] **Schedule 4, Part 1, omit entry for Circumstances Code "C11579"**

[139] **Schedule 4, Part 1, omit entry for Circumstances Code "C11715"**

[140] **Schedule 4, Part 1, omit entry for Circumstances Code "C11716"**

[141] **Schedule 4, Part 1, omit entry for Circumstances Code "C11717"**

[142] **Schedule 4, Part 1, omit entry for Circumstances Code "C11718"**

[143] **Schedule 4, Part 1, omit entry for Circumstances Code "C11761"**

[144] **Schedule 4, Part 1, omit entry for Circumstances Code "C11767"**

[145] **Schedule 4, Part 1, omit entry for Circumstances Code "C11852"**

[146] **Schedule 4, Part 1, omit entry for Circumstances Code "C11853"**

[147] **Schedule 4, Part 1, omit entry for Circumstances Code "C11854"**

[148] **Schedule 4, Part 1, omit entry for Circumstances Code "C11855"**

[149] **Schedule 4, Part 1, omit entry for Circumstances Code "C11903"**

[150] **Schedule 4, Part 1, omit entry for Circumstances Code "C11966"**

[151] **Schedule 4, Part 1, omit entry for Circumstances Code "C12497"**

[152] **Schedule 4, Part 1, omit entry for Circumstances Code "C12507"**

[153] **Schedule 4, Part 1, omit entry for Circumstances Code "C14552"**

[154] **Schedule 4, Part 1, omit entry for Circumstances Code "C14600"**

[155] **Schedule 4, Part 1, omit entry for Circumstances Code "C15757"**

[156] Schedule 4, Part 1, omit entry for Circumstances Code "C15768"

[157] Schedule 4, Part 1, omit entry for Circumstances Code "C15799"

[158] Schedule 4, Part 1, omit entry for Circumstances Code "C15805"

[159] Schedule 4, Part 1, omit entry for Circumstances Code "C15806"

[160] Schedule 4, Part 1, omit entry for Circumstances Code "C15810"

[161] Schedule 4, Part 1, omit entry for Circumstances Code "C15812"

[162] Schedule 4, Part 1, omit entry for Circumstances Code "C16819"

[163] Schedule 4, Part 1, omit entry for Circumstances Code "C16838"

[164] Schedule 4, Part 1, omit entry for Circumstances Code "C16857"

[165] Schedule 4, Part 1, omit entry for Circumstances Code "C16862"

[166] Schedule 4, Part 1, omit entry for Circumstances Code "C16887"

[167] Schedule 4, Part 1, omit entry for Circumstances Code "C16901"

[168] Schedule 4, Part 1, omit entry for Circumstances Code "C16938"

[169] Schedule 4, Part 1, omit entry for Circumstances Code "C16968"

[170] Schedule 4, Part 1, omit entry for Circumstances Code "C16969"

[171] Schedule 4, Part 1, after entry for Circumstances Code "C16976"

insert:

C16977	P16977	CN16977	Secukinumab	Moderate to severe hidradenitis suppurativa Initial treatment - Initial 1 (new patient) Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; or Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete	Compliance with Written Authority Required procedures

	treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; or Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not receive more than 20 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity 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 following a minimum of 16 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. The authority application must be made in writing and must include: (1) details of the proposed prescription(s); 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 Hurley stage grading; and (ii) the AN count; and (iii) the name of the antibiotic/s received for two separate courses each of three months; or (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics. This restriction is intended for induction dosing only. The details of two proposed prescriptions should be submitted with every initial application for this drug.	

				Prescribing the 150 mg presentation: One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats. Prescribing the 300 mg presentation: One prescription should be for the induction doses, containing a quantity of 4 doses of 300 mg and no repeats and the second prescription should be for 1 dose of 300 mg and 3 repeats. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C16979	P16979	CN16979	Adalimumab	Severe Crohn disease Initial treatment - Initial 1 (new patient) Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; or Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate; AND Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment and which is no more than 4 weeks old at the time of application; or Patient must have extensive intestinal inflammation of the small intestine as evidenced by radiological imaging; AND Patient must not receive more than 16 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 gastroenterology (code 82)]; or	Compliance with Written Authority Required procedures

				Must be treated by a paediatrician; or Must be treated by a specialist paediatric gastroenterologist. Patient must be aged 6 to 17 years inclusive. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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). For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, 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; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details 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, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website (www.servicesaustralia.gov.au). 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.	
C16982	P16982	CN16982	Adalimumab	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	Compliance with Authority Required procedures

				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)]; or Must be treated by a paediatrician; or Must be treated by a specialist paediatric gastroenterologist.	
C16991	P16991	CN16991	Adalimumab	Moderate to severe ulcerative colitis Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated 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; or Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years; 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 gastroenterology (code 82)]; or Must be treated by a paediatrician; or Must be treated by a specialist paediatric gastroenterologist. Patient must be 6 years of age or older. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. The measurement of response to the prior course of therapy must be documented in	Compliance with Authority Required procedures - Streamlined Authority Code 16991

				the patient's medical notes. Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised 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. If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
C16993	P16993	CN16993	Adalimumab	Moderate to severe ulcerative colitis First 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; or Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years. Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or Must be treated by a paediatrician; or Must be treated by a specialist paediatric gastroenterologist. Patient must be 6 years of age or older. Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to	Compliance with Authority Required procedures

				17 years) 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. Authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction for patients who: (i) received fewer than 5 repeats at the time of application; and/or (ii) required changes to their dosing regimen during this treatment phase. 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. If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
C16994	P16994	CN16994	Adalimumab	Severe 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 a documented history of severe Crohn disease; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with	Compliance with Written Authority Required procedures

				this drug for this condition more than once in the current treatment cycle; AND Patient must not receive more than 16 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 gastroenterology (code 82)]; or Must be treated by a paediatrician; or Must be treated by a specialist paediatric gastroenterologist. Patient must be aged 6 to 17 years inclusive. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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). 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.	
C16999	P16999	CN16999	Adalimumab	Severe chronic plaque psoriasis Subsequent continuing treatment, Face, hand, foot Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine; AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 16999

				Must be treated by a dermatologist. Patient must have been under 18 years of age at the time of initial treatment with this drug. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. The assessment of response to treatment must be documented in the patient's medical records.	
C17000	P17000	CN17000	Ustekinumab	Severe chronic plaque psoriasis Subsequent continuing treatment (Face, hand, foot) Must be treated by a dermatologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment (Face, hand, foot) - treatment covering week 28 and onwards restrictions; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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 to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or	Compliance with Written Authority Required procedures

				(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The assessment of response to treatment must be provided in this application and documented in the patient's medical records.	
C17001	P17001	CN17001	Etanercept	Severe chronic plaque psoriasis Initial 2 treatment (Whole body) - Change of treatment Must be treated by a dermatologist. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction. Patient must be under 18 years of age. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because: (i) there is an absence of an adequate response to that treatment; or (ii) there was an intolerance to that treatment; or (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above. The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.	Compliance with Authority Required procedures
C17002	P17002	CN17002	Adalimumab	Severe chronic plaque psoriasis First continuing treatment, Whole body Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND The treatment must be as systemic monotherapy; or	Compliance with Written Authority Required procedures

				The treatment must be in combination with methotrexate; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a dermatologist. Patient must have been under 18 years of age at the time of initial treatment with this drug. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for 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. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (a) details of the proposed prescription(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 4 weeks old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.	
C17003	P17003	CN17003	Adalimumab	Severe chronic plaque psoriasis First continuing treatment, Face, hand, foot Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must have demonstrated an adequate response to treatment with this drug;	Compliance with Written Authority Required procedures

				AND Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a dermatologist. Patient must have been under 18 years of age at the time of initial treatment with this drug. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for 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. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (a) details of the proposed prescription(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 4 weeks old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.	
C17005	P17005	CN17005	Adalimumab	Severe chronic plaque psoriasis Initial 2 treatment (Whole body) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must have received prior PBS-subsidised treatment with a biological medicine	Compliance with Written Authority Required procedures

				for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 17 weeks of treatment under this restriction. Must be treated by a dermatologist. Patient must be under 18 years of age. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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). Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application. Response to preceding supply: An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. Change in therapy: If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because: (i) there is an absence of an adequate response to that treatment; or (ii) there was an intolerance to that treatment; or (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above Recommencing therapy: If the patient is recommencing therapy, in relation to the last administered dose, state whether there was: (i) an absence of an adequate response; or (ii) an intolerance to that treatment; or (iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above. The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.	
C17009	P17009	CN17009	Dupilumab	Uncontrolled severe asthma	Compliance with Written

	Continuing treatment Patient must have a documented history of either: (i) severe asthma, (ii) severe allergic asthma; AND Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician. Patient must be aged 6 to less than 12 years. An adequate response to this biological medicine is defined as: (a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score of at least 0.5 from baseline, OR (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline. All applications for continuing treatment with this biological medicine must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 20 weeks after the first PBS-subsidised dose of this biological medicine so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The first assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition. A patient who fails to demonstrate a response treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle. At the time of authority application, medical practitioners should request the	Authority Required procedures

				appropriate quantity and number of repeats to provide for a continuing course of dupilumab, sufficient for 24 weeks therapy. 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) maintenance oral corticosteroid dose; and (b) Asthma Control Questionnaire (ACQ-5) score; or (c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score. The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.	
C17016	P17016	CN17016	Dupilumab	Uncontrolled severe asthma Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy) Patient must not have received PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; OR Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; AND Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility, (b) airway hyperresponsiveness, (c) peak expiratory flow (PEF) variability; AND Patient must have a duration of asthma of at least 1 year; AND Patient must have total serum human immunoglobulin E of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the last 12 months; OR Patient must have blood eosinophil count of at least 150 cells per microlitre in the last 12 months; OR Patient must have a fractional exhaled nitrous oxide of at least 20 ppb in the last 12 months; AND	Compliance with Written Authority Required procedures

	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 Patient must be under the care of the same physician for at least 6 months; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for either: (i) severe asthma, (ii) severe allergic asthma. Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician. Patient must be aged 6 to less than 12 years. Optimised asthma therapy includes: (i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; AND (ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in 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 initial IgE assessment, blood eosinophil count or fractional exhaled nitrous oxide measurement must be no more than 12 months old at the time of 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 (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used), AND (b) while receiving optimised asthma therapy in the previous 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) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 28 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the last dose of biological medicine, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition. A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine 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 2 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. At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of dupilumab of up to 32 weeks. 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 of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and (b) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (c) the IgE, blood eosinophil or the fractional exhaled nitrous oxide result and date; and (d) Asthma Control Questionnaire (ACQ-5) score; or (e) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

C17017	P17017	CN17017	Palovarotene	Fibrodysplasia ossificans progressiva (FOP) Chronic treatment Patient must have a diagnosis of FOP, confirmed by genetic testing. Must be treated by a specialist medical practitioner experienced in the diagnosis and management of FOP; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of FOP. Patient must be a female aged 8 years or older; or Patient must be a male aged 10 years or older. At the time of the authority application, the medical practitioner must request the appropriate combination of packs to provide treatment at the recommended dose for chronic treatment, based on the age and weight of the patient, adequate for 4 weeks according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised. Appropriate genetic testing constitutes testing for a pathogenic variant of the Activin A receptor type I (ACVR1) gene. Confirm that evidence of the presence of a pathogenic mutation of the ACVR1 gene is documented/retained in the patient's medical records once only with the first PBS prescription. 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
C17018	P17018	CN17018	Palovarotene	Fibrodysplasia ossificans progressiva (FOP) Flare-up (acute) treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must be experiencing a FOP flare-up; or Patient must be at high risk of a FOP flare-up. Must be treated by a specialist medical practitioner experienced in the diagnosis and management of FOP; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of FOP. Patient must be a female aged 8 years or older; or Patient must be a male aged 10 years or older. Flare-up treatment should begin at the onset of the first symptom indicative of a FOP flare-up or substantial high-risk traumatic event likely to lead to a flare-up. Symptoms of a FOP flareup typically include but are not limited to localised pain, soft tissue	Compliance with Authority Required procedures - Streamlined Authority Code 17018

				swelling/inflammation, redness, warmth, decreased joint range of motion, and stiffness. Examples of a high risk substantial traumatic event include surgery, intramuscular immunisation, mandibular blocks for dental work, muscle fatigue, blunt muscle trauma from bumps, bruises, falls, or influenza-like viral illnesses. At the time of the authority application, the medical practitioner must request the appropriate combination of packs to provide treatment at the recommended dose for flare-up treatment based on the age and weight of the patient, adequate for 12 weeks of treatment or in the presence of persistent flare-up symptoms to extend treatment in 4-week intervals according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. If the patient experiences another flare-up (i.e., new flare-up location or marked worsening of the original flare-up) at any time during flare-up treatment, the flare-up 12-week treatment should be restarted.	
C17019	P17019	CN17019	Ruxolitinib	Polycythemia vera Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have achieved and maintained a response to treatment with this drug for this condition. Patient must be at least 18 years of age.	Compliance with Authority Required procedures
C17025	P17025	CN17025	Secukinumab	Moderate to severe hidradenitis suppurativa Initial treatment - Initial 1 (new patient) Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; or Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; or Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; AND Patient must not have received PBS-subsidised treatment with a biological medicine	Compliance with Written Authority Required procedures

		for this condition; AND Patient must not receive more than 20 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity 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 following a minimum of 16 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. The authority application must be made in writing and must include: (1) details of the proposed prescription(s); 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 Hurley stage grading; and (ii) the AN count; and (iii) the name of the antibiotic/s received for two separate courses each of three months; or (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics. The details of two proposed prescriptions should be submitted with every initial application for this drug. Prescribing the 150 mg presentation: One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats. Prescribing the 300 mg presentation: One prescription should be for the induction doses, containing a quantity of 4 doses of 300 mg and no repeats and the second prescription should be for 1 dose of 300 mg and 3 repeats. Serious adverse reaction of a severity resulting in the necessity for permanent

				withdrawal of treatment is not considered as a treatment failure.	
C17026	P17026	CN17026	Secukinumab	Moderate to severe hidradenitis suppurativa 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 had 3 treatment failures within this treatment cycle to PBS-subsidised biological medicines for this condition; AND Patient must not receive more than 20 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. An application for a patient who has received PBS-subsidised treatment with this drug, has not experienced treatment failure, and 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 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. The authority application must be made in writing and must include: (1) details of the proposed prescription(s); 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 Hurley stage grading; and (ii) the AN count.	Compliance with Written Authority Required procedures

				The details of two proposed prescriptions should be submitted with every initial application for this drug. Prescribing the 150 mg presentation: One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats. Prescribing the 300 mg presentation: One prescription should be for the induction doses, containing a quantity of 4 doses of 300 mg and no repeats and the second prescription should be for 1 dose of 300 mg and 3 repeats.	
C17028	P17028	CN17028	Secukinumab	Moderate to severe hidradenitis suppurativa Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must not receive more than 20 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 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. The authority application must be made in writing and must include:	Compliance with Written Authority Required procedures

				(1) details of the proposed prescription(s); 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 Hurley stage grading; and (ii) the AN count. The details of two proposed prescriptions should be submitted with every initial application for this drug. Prescribing the 150 mg presentation: One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats. Prescribing the 300 mg presentation: One prescription should be for the induction doses, containing a quantity of 4 doses of 300 mg and no repeats and the second prescription should be for 1 dose of 300 mg and 3 repeats.	
C17030	P17030	CN17030	Adalimumab	Moderate to severe ulcerative colitis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available 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 gastroenterology (code 82)]; or Must be treated by a paediatrician. or Must be treated by a specialist paediatric gastroenterologist.	Compliance with Authority Required procedures
C17031	P17031	CN17031	Adalimumab	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	Compliance with Written Authority Required procedures

	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 (for a child, 1 to 2 mg/kg up to 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 if an adult patient; 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); or Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years. Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or Must be treated by a paediatrician; or Must be treated by a specialist paediatric gastroenterologist. Patient must be 6 years of age or older. The authority application must be made in writing and must include: (1) details of the proposed prescription(s); 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 or Paediatric Ulcerative Colitis Activity Index (PUCAI) 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, partial Mayo clinic or Paediatric Ulcerative Colitis Activity

				Index (PUCAI) score must be no more than 4 weeks old at the time of application. A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. 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. 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. Details of the accepted toxicities including severity can be found on the Services Australia website.	
C17032	P17032	CN17032	Adalimumab	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; or Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years; 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; or 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 more than once if aged 6 to 17 years. Must be treated by a gastroenterologist (code 87); or	Compliance with Written Authority Required procedures

	Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or Must be treated by a paediatrician; or Must be treated by a specialist paediatric gastroenterologist. Patient must be 6 years of age or older. The authority application must be made in writing and must include: (1) details of the proposed prescription(s); 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 or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. 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 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. If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine

				treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
C17039	P17039	CN17039	Ustekinumab	Severe chronic plaque psoriasis Initial 2 treatment (Face, hand, foot) - Change or recommencement of treatment after a break in biological medicine of less than 5 years Must be treated by a dermatologist. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be under 18 years of age. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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). Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application. Response to preceding supply: An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or is sustained at this level, when compared with the baseline value for this treatment cycle. Change in therapy: If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because: (i) there is an absence of an adequate response to that treatment; or	Compliance with Written Authority Required procedures

				(ii) there was an intolerance to that treatment; or (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above Recommencing therapy: If the patient is recommencing therapy, in relation to the last administered dose, state whether there was: (i) an absence of an adequate response; or (ii) an intolerance to that treatment; or (iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above. The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.	
C17042	P17042	CN17042	Adalimumab	Severe chronic plaque psoriasis Balance of supply - Initial 1, 2 or 3 treatment (Whole body, or, face/hand/foot) The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND The treatment must provide no more than the balance of 17 weeks of treatment available under any of the initial treatment phases. Must be treated by a dermatologist; AND Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 3 doses available under any of the initial treatment phases (regardless of the affected body area): (i) Initial 1, (ii) Initial 2, (iii) Initial 3.	Compliance with Authority Required procedures
C17043	P17043	CN17043	Adalimumab	Severe chronic plaque psoriasis Initial 1 treatment (Whole body) - biological medicine-naive patient Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND	Compliance with Written Authority Required procedures

				Patient must not receive more than 17 weeks of treatment under this restriction. Must be treated by a dermatologist. Patient must be under 18 years of age. Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application. Where intolerance to phototherapy, methotrexate and/or acitretin 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. Details of the accepted toxicities including severity can be found on the Services Australia website. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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 indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy: (a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy. A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of: (i) the name of each prior therapy trialled that meets the above requirements - state at least 2; (ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies); (iii) the PASI score that followed each prior therapy trialled; (iv) the date the PASI scores were determined. Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.	
C17044	P17044	CN17044	Adalimumab	Severe chronic plaque psoriasis Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient	Compliance with Written Authority Required

	Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND Patient must not receive more than 17 weeks of treatment under this restriction. Must be treated by a dermatologist. Patient must be under 18 years of age. Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application. Where intolerance to phototherapy, methotrexate and/or acitretin 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. Details of the accepted toxicities including severity can be found on the Services Australia website. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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 indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy: (a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or (b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy Provide in this authority application, and document in the patient's medical records,	procedures

				each of: (i) the name of each prior therapy trialled that meets the above requirements - state at least 2; (ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies); (iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled; (iv) the dates that response assessments were determined. Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment: (v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe); (vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.	
C17045	P17045	CN17045	Adalimumab	Severe chronic plaque psoriasis Initial 2 treatment (Face, hand, foot) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND Patient must not receive more than 17 weeks of treatment under this restriction. Must be treated by a dermatologist. Patient must be under 18 years of age. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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). Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.	Compliance with Written Authority Required procedures

				Response to preceding supply: An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or is sustained at this level, when compared with the baseline value for this treatment cycle. Change in therapy: If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because: (i) there is an absence of an adequate response to that treatment; or (ii) there was an intolerance to that treatment; or (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above Recommencing therapy: If the patient is recommencing therapy, in relation to the last administered dose, state whether there was: (i) an absence of an adequate response; or (ii) an intolerance to that treatment; or (iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above. The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.	
C17046	P17046	CN17046	Adalimumab	Severe chronic plaque psoriasis Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle; AND The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; or The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot'; AND	Compliance with Written Authority Required procedures

				Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; or The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must not receive more than 17 weeks of treatment under this restriction. Must be treated by a dermatologist. Patient must be under 18 years of age. The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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).	
C17047	P17047	CN17047	Dupilumab	Chronic severe atopic dermatitis Initial treatment of the whole body Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands; AND The treatment must be the sole PBS-subsidised biological medicine for this PBS indication; AND	Compliance with Authority Required procedures

				Patient must not have experienced an inadequate response to this biological medicine in this PBS indication. Must be treated by a dermatologist; or Must be treated by a clinical immunologist. Patient must be at least 12 years of age. State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application. Acceptable scores can be: (a) current scores; or (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication. The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records. Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records.	
C17052	P17052	CN17052	Ruxolitinib	Polycythemia vera First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised treatment for this condition; AND Patient must have achieved and maintained a response to treatment with this drug for this condition. Patient must be at least 18 years of age. A response to treatment is defined as: (i) Maintaining a haematocrit level of less than 45% without relying on phlebotomy and which was measured at least 12 weeks after the most recent phlebotomy procedure (if performed to reduce red blood cell levels); or (ii) Ability to demonstrate or maintain a normal platelet count of less than or equal to 400 x 109/L; or (iii) The absence of palpable splenomegaly. The following must be documented in the patient's medical records: (a) details (dates, unique identifying number/code, or provider number) of the pathology report confirming the patient has achieved and maintained a response within 48 weeks of treatment initiation; or (b) confirmation that the patient does not have palpable splenomegaly.	Compliance with Authority Required procedures

C17053	P17053	CN17053	Ruxolitinib	Polycythemia vera Initial treatment Patient must be resistant to hydroxycarbamide (hydroxyurea); or Patient must have an intolerance to hydroxycarbamide (hydroxyurea) of a severity necessitating permanent treatment withdrawal; or Patient must have developed a clinically important adverse event/contraindication to hydroxycarbamide (hydroxyurea) as defined in the TGA-approved Product Information necessitating permanent treatment withdrawal; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition. Patient must be at least 18 years of age. Hydroxycarbamide (hydroxyurea) resistance is defined as a minimum of 12 consecutive weeks treatment at a dose of at least 1.5 grams/day or at the maximum tolerated that still results in one of the following: (i) the need to reduce haematocrit levels to below 45% through phlebotomy; or (ii) a platelet count greater than 400 x 109/L and a white blood cell count greater than 10 x 109/L If applicable, details of prior systemic treatment with hydroxycarbamide (hydroxyurea) that caused either (i) an intolerance, (ii) an adverse event as listed in the TGA-approved Product Information, or (iii) a contraindication as listed in the TGA-approved Product Information necessitating permanent treatment withdrawal should be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; and (ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Authority Required procedures
C17054	P17054	CN17054	Ruxolitinib	Polycythemia vera Balance of Initial treatment - up to 48 weeks Patient must have received this drug as their most recent course of PBS-subsidised treatment for this condition; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures

C17057	P17057	CN17057	Secukinumab	Moderate to severe hidradenitis suppurativa 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 had 3 treatment failures within this treatment cycle to PBS-subsidised biological medicines for this condition; AND Patient must not receive more than 20 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. An application for a patient who has received PBS-subsidised treatment with this drug, has not experienced treatment failure, and 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 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. The authority application must be made in writing and must include: (1) details of the proposed prescription(s); 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 Hurley stage grading; and (ii) the AN count. The details of two proposed prescriptions should be submitted with every initial application for this drug.	Compliance with Written Authority Required procedures

				Prescribing the 150 mg presentation: One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats. Prescribing the 300 mg presentation: One prescription should be for the induction doses, containing a quantity of 4 doses of 300 mg and no repeats and the second prescription should be for 1 dose of 300 mg and 3 repeats. This restriction is intended for induction dosing only.	
C17058	P17058	CN17058	Secukinumab	Moderate to severe hidradenitis suppurativa Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must not receive more than 20 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 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. The authority application must be made in writing and must include: (1) details of the proposed prescription(s); and	Compliance with Written Authority Required procedures

				(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes: (i) the Hurley stage grading; and (ii) the AN count. The details of two proposed prescriptions should be submitted with every initial application for this drug. Prescribing the 150 mg presentation: One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats. Prescribing the 300 mg presentation: One prescription should be for the induction doses, containing a quantity of 4 doses of 300 mg and no repeats and the second prescription should be for 1 dose of 300 mg and 3 repeats. This restriction is intended for induction dosing only.	
C17065	P17065	CN17065	Adalimumab	Severe chronic plaque psoriasis Subsequent continuing treatment, Whole body Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine; AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Must be treated by a dermatologist. Patient must have been under 18 years of age at the time of initial treatment with this drug. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. The assessment of response to treatment must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 17065

C17067	P17067	CN17067	Ustekinumab	Severe chronic plaque psoriasis Initial 2 treatment (Whole body) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years Must be treated by a dermatologist. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be under 18 years of age. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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). Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application. Response to preceding supply: An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. Change in therapy: If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because: (i) there is an absence of an adequate response to that treatment; or (ii) there was an intolerance to that treatment; or (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above Recommencing therapy: If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:	Compliance with Written Authority Required procedures

				(i) an absence of an adequate response; or (ii) an intolerance to that treatment; or (iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above. The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.	
C17068	P17068	CN17068	Ustekinumab	Severe chronic plaque psoriasis Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years Must be treated by a dermatologist. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle; AND The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; or The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot'; AND Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; or The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be under 18 years of age. The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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	Compliance with Written Authority Required procedures

				Advice).	
C17069	P17069	CN17069	Etanercept	Severe chronic plaque psoriasis Initial 2 treatment (Face, hand, foot) - Change of treatment Must be treated by a dermatologist. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction. Patient must be under 18 years of age. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value. In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because: (i) there is an absence of an adequate response to that treatment; or (ii) there was an intolerance to that treatment; or (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above. The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.	Compliance with Authority Required procedures
C17070	P17070	CN17070	Ustekinumab	Severe chronic plaque psoriasis Initial 1 treatment (Whole body) - biological medicine-naive patient Must be treated by a dermatologist. Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; AND	Compliance with Written Authority Required procedures

	The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must have lesions present for at least 6 months from the time of initial diagnosis; AND Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be under 18 years of age. Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application. Where intolerance to phototherapy, methotrexate and/or acitretin 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. Details of the accepted toxicities including severity can be found on the Services Australia website. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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 indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy: (a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy. A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of: (i) the name of each prior therapy trialled that meets the above requirements - state at least 2; (ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

				(iii) the PASI score that followed each prior therapy trialled; (iv) the date the PASI scores were determined. Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.	
C17071	P17071	CN17071	Ustekinumab	Severe chronic plaque psoriasis Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient Must be treated by a dermatologist. Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis; AND Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be under 18 years of age. Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application. Where intolerance to phototherapy, methotrexate and/or acitretin 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. Details of the accepted toxicities including severity can be found on the Services Australia website. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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 indicates failure to achieve an adequate response to prior	Compliance with Written Authority Required procedures

				phototherapy/methotrexate/acitretin therapy: (a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or (b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy Provide in this authority application, and document in the patient's medical records, each of: (i) the name of each prior therapy trialled that meets the above requirements - state at least 2; (ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies); (iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled; (iv) the dates that response assessments were determined. Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment: (v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe); (vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.	
C17072	P17072	CN17072	Dupilumab	Uncontrolled severe asthma Initial treatment - Initial 2 (Change of treatment) Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; OR Patient must have had a blood eosinophil count of at least 150 cells per microlitre no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; OR Patient must have had a fractional exhaled nitrous oxide of at least 20 ppb no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; AND Patient must not receive more than 32 weeks of treatment under this restriction; AND	Compliance with Written Authority Required procedures

		Patient must be under the care of the same physician for at least 6 months; AND Patient must have received prior PBS-subsidised treatment with a biological medicine in this treatment cycle for either: (i) severe asthma, (ii) severe allergic asthma; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for either: (i) severe asthma, (ii) severe allergic asthma. Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician. Patient must be aged 6 to less than 12 years. An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma or severe allergic asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made no 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 Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) 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 submitted 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 submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine. A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine 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 2 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. At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy. 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) the IgE, blood eosinophil or fractional exhaled nitrous oxide result and date; and (b) Asthma Control Questionnaire (ACQ-5) score; or (c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score. (d) the details of prior biological medicine treatment including the details of date and duration of treatment; and (e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).	
C17073	P17073	CN17073	Dupilumab	Uncontrolled severe asthma Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy), Initial treatment - Initial 2 (Change of treatment), Continuing treatment, or transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements - Balance of Supply in a patient aged 6 to 12 years Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy) restriction to complete 32 weeks of treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 2 (Change of treatment) restriction to complete 32 weeks of treatment; OR Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; OR Patient must have received insufficient therapy with this drug for this condition under	Compliance with Authority Required procedures

				the transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements restriction to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 32 weeks treatment available under the Initial 1 and Initial 2 restriction; OR The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing and transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements restriction. Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.	
C17076	P17076	CN17076	Dupilumab	Chronic severe atopic dermatitis Initial treatment of the face and/or hands The condition must have at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; or The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands; AND The treatment must be the sole PBS-subsidised biological medicine for this PBS indication; AND Patient must not have experienced an inadequate response to this biological medicine in this PBS indication. Must be treated by a dermatologist; or Must be treated by a clinical immunologist. Patient must be at least 12 years of age. State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for: (i) erythema, (ii) oedema/papulation,	Compliance with Authority Required procedures

				(iii) excoriation, (iv) lichenification Acceptable scores can be: (a) current scores; or (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication. State the percentage face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores. The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records. Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records.	
C17077	P17077	CN17077	Adalimumab	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 if an adult patient; 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); or Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years. Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or Must be treated by a paediatrician; or Must be treated by a specialist paediatric gastroenterologist. Patient must be 6 years of age or older. The authority application must be made in writing and must include:	Compliance with Written Authority Required procedures

				(1) details of the proposed prescription(s); 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 or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application. A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated. 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. Details of the accepted toxicities including severity can be found on the Services Australia website.	
C17080	P17080	CN17080	Ustekinumab	Severe chronic plaque psoriasis First continuing treatment (Whole body) - treatment covering week 28 and onwards	Compliance with Written Authority Required procedures

				Must be treated by a dermatologist. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine; AND Patient must have demonstrated an adequate response to treatment; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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 to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The assessment of response to treatment must be provided in this application and documented in the patient's medical records. The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.	
C17093	P17093	CN17093	Ustekinumab	Severe chronic plaque psoriasis First continuing treatment (Face, hand, foot) - treatment covering week 28 and onwards Must be treated by a dermatologist. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine; AND Patient must have demonstrated an adequate response to treatment; AND Patient must not receive more than 24 weeks of treatment per continuing treatment	Compliance with Written Authority Required procedures

				course authorised under this restriction. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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 to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The assessment of response to treatment must be provided in this application and documented in the patient's medical records.	
C17094	P17094	CN17094	Ustekinumab	Severe chronic plaque psoriasis Subsequent continuing treatment (Whole body) Must be treated by a dermatologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment (Whole body) - treatment covering week 28 and onwards restrictions; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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 to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment	Compliance with Written Authority Required procedures

				cycle. The assessment of response to treatment must be provided in this application and documented in the patient's medical records. The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.	
C17104	P17104	CN17104	Adalimumab	Severe Crohn disease First continuing treatment of Crohn disease in a paediatric patient Patient must have a documented history of severe Crohn disease; AND Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have both: (i) a total PCDAI score of 40 points or less, and (ii) a reduction in PCDAI score by at least 15 points from baseline value; or Patient must have an adequate response to this drug defined as 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; 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 gastroenterology (code 82)]; or Must be treated by a paediatrician; or Must be treated by a specialist paediatric gastroenterologist. Patient must be aged 6 to 17 years inclusive. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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 assessment of response must be no more than 4 weeks old at the time of application.	Compliance with Written Authority Required procedures

				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. Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. Authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction for patients who: (i) received fewer than 5 repeats at the time of application; and/or (ii) required changes to their dosing regimen during this treatment phase.	
C17106	P17106	CN17106	Adalimumab	Severe Crohn disease Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had 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 confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist; AND Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40; or Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease that is no more than 4 weeks old at the time of application; AND Patient must not receive more than 16 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)]; or Must be treated by a paediatrician; or Must be treated by a specialist paediatric gastroenterologist. Patient must be aged 6 to 17 years inclusive. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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). For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, 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; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. The PCDAI assessment 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 made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated. 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.	
C17113	P17113	CN17113	Dupilumab	Uncontrolled severe asthma 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 September 2025; AND Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist; (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility, (ii) airway hyperresponsiveness, (iii) peak expiratory flow (PEF) variability; AND	Compliance with Written Authority Required procedures

	Patient must have had a duration of asthma of at least 1 year prior to commencement of non-PBS-subsidised treatment with this drug; AND Patient must have had a documented total serum human immunoglobulin E of at least 30 IU/mL measured no more than 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR Patient must have had a blood eosinophil count of at least 150 cells per microlitre in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had a fractional exhaled nitrous oxide of at least 20 ppb in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; AND Patient must have documented a failure to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated or sustained an adequate response to treatment with this drug if the patient has received at least 28 weeks of treatment with this drug for this condition; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician. Patient must have been aged 6 to less than 12 years prior to starting non-PBS-subsidised treatment with this drug. Optimised asthma therapy includes: (i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; AND (ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in 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.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

The following initiation criteria indicate failure to achieve adequate control with optimised asthma therapy 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 prior to non-PBS-subsidised treatment with this drug for this condition (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used), AND(b) while receiving optimised asthma therapy in the prior to non-PBS-subsidised treatment with this drug for this condition 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) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate to determine whether the patient has achieved or sustained an adequate response to non-PBS subsidised treatment, must be conducted immediately (no later than 4 weeks after the last dose of non-PBS-subsidised treatment) prior to this application if the treatment duration has been at least 28 weeks

All applications for continuing treatment with this biological medicine must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 20 weeks after the first dose of PBS-subsidised treatment with this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their

				current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this drug for this condition. A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine 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 2 biological medicines within the same treatment cycle. The length of the break in therapy is measured from the date of 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. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of dupilumab, sufficient for 24 weeks of therapy. 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) prior optimised asthma drug therapy (date of commencement and duration of therapy); and (b) IgE, blood eosinophils or fractional exhaled nitrous oxide results and date from prior to initiating non-PBS-subsidised treatment with this drug; and (c) date of commencing non-PBS-subsidised treatment with this drug for this condition. (d) If applicable, maintenance oral corticosteroid dose; and (e) If applicable, the Asthma Control Questionnaire (ACQ-5) scores, including the date of assessment of the patient's symptoms; or (f) If applicable, the Asthma Control Questionnaire interviewer administered version (ACQ-IA) scores, including the date of assessment of the patient's symptoms.	
C17114	P17114	CN17114	Adalimumab	Severe Crohn disease Subsequent continuing treatment of Crohn disease in a paediatric patient Patient must have a documented history of severe Crohn disease; AND Patient must have previously received PBS-subsidised treatment with this drug for this	Compliance with Authority Required procedures - Streamlined Authority Code 17114

	condition under the First continuing treatment restriction; AND Patient must have both: (i) a total PCDAI score of 40 points or less, and (ii) a reduction in PCDAI score by at least 15 points from baseline value; or Patient must have an adequate response to this drug defined as 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; 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 gastroenterology (code 82)]; or Must be treated by a paediatrician; or Must be treated by a specialist paediatric gastroenterologist. Patient must be aged 6 to 17 years inclusive. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. The assessment of response must be no more than 4 weeks old at the time of prescribing. Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

[172] Schedule 5, entry for Abiraterone *[GRP-29273]*

insert in the column headed "Brand" after entry for the brand "Abiraterone-Teva": ABIRATERONE VIATRIS

[173] Schedule 5, entry for Abiraterone *[GRP-29283]*

insert in the column headed "Brand" after entry for the brand "Abiraterone-Teva": ABIRATERONE VIATRIS

[174] Schedule 5, entries for Acarbose

omit:

Acarbose	GRP-29491	Tablet 50 mg (S19A)	Oral	Acarbose 50 mg tablets (Morningside, UK)

[175] Schedule 5, entries for Aciclovir

substitute:

Aciclovir	GRP-15446	Tablet 200 mg	Oral	Aciclovir GH Aciclovir Sandoz ACICLOVIR-WGR APO-Aciclovir ARX-ACICLOVIR
Aciclovir	GRP-19838	Tablet 800 mg	Oral	Aciclovir Sandoz ACICLOVIR-WGR APO-Aciclovir ARX-ACICLOVIR
Aciclovir	GRP-22959	Eye ointment 30 mg per g, 4.5 g	Application to the eye	ViruPOS XOROX

[176] Schedule 5, entries for Allopurinol

substitute:

Allopurinol	GRP-15579	Tablet 100 mg	Oral	Allopurinol Sandoz ALLOPURINOL-WGR Allosig APO-ALLOPURINOL NOUMED ALLOPURINOL Progout Viatris Progout 100 Zyloprim
Allopurinol	GRP-19808	Tablet 300 mg	Oral	Allopurinol Sandoz ALLOPURINOL-WGR Allosig APO-ALLOPURINOL NOUMED ALLOPURINOL Progout 300 Zyloprim

[177] Schedule 5, entries for Amisulpride

substitute:

Amisulpride	GRP-19672	Tablet 200 mg	Oral	Amisulpride Sandoz Pharma AMISULPRIDE-WGR

				APO-Amisulpride Solian 200 Sulprix
Amisulpride	GRP-19732	Tablet 400 mg	Oral	Amisulpride Sandoz Pharma AMISULPRIDE-WGR APO-Amisulpride Solian 400 Sulprix
Amisulpride	GRP-19930	Tablet 100 mg	Oral	Amisulpride Sandoz Pharma AMISULPRIDE-WGR APO-Amisulpride Solian 100 Sulprix

[178] Schedule 5, entry for Amlodipine *[GRP-19712]*

substitute:

Amlodipine	GRP-19712	Tablet 5 mg (as besilate)	Oral	Amlo 5 Amlodipine GH Amlodipine Sandoz AMLODIPINE-WGR APO-Amlodipine APX-AMLODIPINE Blooms Amlodipine Nordip Norvasc NOUMED AMLODIPINE Pharmacor Amlodipine

[179] Schedule 5, entry for Amlodipine *[GRP-19809]*

omit from the column headed "Brand": Blooms the Chemist Amlodipine

[180] Schedule 5, entry for Amoxicillin with clavulanic acid *[GRP-20135]*

omit from the column headed "Brand": Amoxycillin/Clavulanic Acid 500/125 APOTEX

[181] Schedule 5, after entry for Baclofen *[GRP-19941]*

insert:

Benzathine benzylpenicillin	GRP-28213	Powder for injection 1,200,000 units with diluent 4 mL (S19A)	Injection	Lentocilin S 1200 (Portugal)

[182] Schedule 5, entries for Candesartan with hydrochlorothiazide

substitute:

Candesartan with hydrochlorothiazide	GRP-19559	Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg	Oral	Adesan HCT 32/25 APO-Candesartan HCTZ 32/25 Atacand Plus 32/25 BTC Candesartan HCT CANDESAN COMBI 32/25 Candesartan/HCT Sandoz CANDESARTAN HCTZ-WGR 32/25 NOUMED CANDESARTAN/HCT
Candesartan with hydrochlorothiazide	GRP-19563	Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 g	Oral	Adesan HCT 32/12.5 APO-Candesartan HCTZ 32/12.5 Atacand Plus 32/12.5 BTC Candesartan HCT CANDESAN COMBI 32/12.5 Candesartan/HCT Sandoz CANDESARTAN HCTZ-WGR 32/25 NOUMED CANDESARTAN/HCT
Candesartan with hydrochlorothiazide	GRP-19567	Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg	Oral	Adesan HCT 16/12.5 APO-Candesartan HCTZ 16/12.5 Atacand Plus 16/12.5 BTC Candesartan HCT CANDESAN COMBI 16/12.5 Candesartan/HCT Sandoz CANDESARTAN HCTZ-WGR 16/12.5 NOUMED CANDESARTAN/HCT

[183] Schedule 5, entries for Celecoxib

substitute:

Celecoxib	GRP-19618	Capsule 100 mg	Oral	APX-Celecoxib Blooms Celecoxib Celaxib Celebrex Celecoxib GH Celecoxib Sandoz CELECOXIB-WGR Celexi

Celecoxib	GRP-19623	Capsule 200 mg	Oral	APX-Celecoxib Blooms Celecoxib Celaxib Celebrex Celecoxib GH Celecoxib Sandoz CELECOXIB-WGR Celexi

[184] Schedule 5, entry for Denosumab *[GRP-29945]*

insert as the first entry in the column headed "Brand": GANVADO

[185] Schedule 5, entry for Denosumab *[GRP-29965]*

insert as the first entry in the column headed "Brand": CORORA

[186] Schedule 5, after entry for Duloxetine *[GRP-19957]*

insert:

Dupilumab	GRP-30055	Injection 300 mg in 2 mL single dose pre-filled pen	Injection	Dupixent
Dupilumab	GRP-30055	Injection 300 mg in 2 mL single dose pre-filled syringe	Injection	Dupixent
Dupilumab	GRP-30068	Injection 200 mg in 1.14 mL single dose pre-filled pen	Injection	Dupixent
Dupilumab	GRP-30068	Injection 200 mg in 1.14 mL single dose pre-filled syringe	Injection	Dupixent

[187] Schedule 5, entries for Fentanyl

omit

Fentanyl	GRP-15510	Transdermal patch 7.65 mg	Transdermal	Denpax

[188] Schedule 5, entries for Fentanyl

omit:

Fentanyl	GRP-15510	Transdermal patch 12.375 mg	Transdermal	Fenpatch 75

[189] Schedule 5, entries for Fentanyl

omit:

Fentanyl	GRP-15577	Transdermal patch 2.55 mg	Transdermal	Denpax

[190] Schedule 5, entries for Fentanyl

omit:

Fentanyl	GRP-15577	Transdermal patch 4.125 mg	Transdermal	Fenpatch 25

[191] Schedule 5, entries for Fentanyl

omit:

Fentanyl	GRP-15659	Transdermal patch 5.10 mg	Transdermal	Denpax

[192] Schedule 5, entries for Fentanyl

omit:

Fentanyl	GRP-15659	Transdermal patch 8.25 mg	Transdermal	Fenpatch 50

[193] Schedule 5, entries for Fentanyl

omit:

Fentanyl	GRP-15747	Transdermal patch 10.20 mg	Transdermal	Denpax

[194] Schedule 5, entries for Fentanyl

omit:

Fentanyl	GRP-15747	Transdermal patch 16.5 mg	Transdermal	Fenpatch 100

[195] Schedule 5, entries for Fentanyl

omit:

Fentanyl	GRP-15898	Transdermal patch 1.28 mg	Transdermal	Denpax

[196] Schedule 5, entries for Fentanyl

omit:

Fentanyl	GRP-15898	Transdermal patch 2.063 mg	Transdermal	Fenpatch 12

[197] Schedule 5, entry for Imatinib in the form Capsule 100 mg (as mesilate)

omit from the column headed "Brand": Imatinib-APOTEX

[198] Schedule 5, entries for Irbesartan

substitute:

Irbesartan	GRP-19646	Tablet 75 mg	Oral	Abisart 75 APO-Irbesartan AVSARTAN Blooms Irbesartan Irbesartan Sandoz IRBESARTAN-WGR Noumed Irbesartan
Irbesartan	GRP-19659	Tablet 150 mg	Oral	Abisart 150 APO-Irbesartan Avapro AVSARTAN Blooms Irbesartan Irbesartan Sandoz IRBESARTAN-WGR Karvea Noumed Irbesartan
Irbesartan	GRP-19742	Tablet 300 mg	Oral	Abisart 300 APO-Irbesartan Avapro AVSARTAN Blooms Irbesartan Irbesartan Sandoz IRBESARTAN-WGR Karvea Noumed Irbesartan

[199] Schedule 5, entries for Irbesartan with hydrochlorothiazide

substitute:

Irbesartan with hydrochlorothiazide	GRP-19699	Tablet 300 mg-25 mg	Oral	Abisart HCTZ 300/25 APO-Irbesartan HCTZ Avapro HCT 300/25 AVSARTAN HCT 300/25 Irbesartan/HCT Sandoz

				IRBESARTAN HCTZ-WGR 300/25 Karvezide 300/25
Irbesartan with hydrochlorothiazide	GRP-19743	Tablet 300 mg-12.5 mg	Oral	Abisart HCTZ 300/12.5 APO-Irbesartan HCTZ Avapro HCT 300/12.5 AVSARTAN HCT 300/12.5 Irbesartan/HCT Sandoz IRBESARTAN HCTZ-WGR 300/12.5 Karvezide 300/12.5
Irbesartan with hydrochlorothiazide	GRP-19958	Tablet 150 mg-12.5 mg	Oral	Abisart HCTZ 150/12.5 APO-Irbesartan HCTZ Avapro HCT 150/12.5 AVSARTAN HCT 150/12.5 Irbesartan/HCT Sandoz IRBESARTAN HCTZ-WGR 150/12.5 Karvezide 150/12.5

[200] Schedule 5, entry for Lamivudine *[GRP-19748]*

insert in the column headed "Brand" after entry for the brand "Lamivudine Alphapharm": Lamivudine Viatris

[201] Schedule 5, entries for Methylphenidate

omit:

Methylphenidate	GRP-27208	Capsule containing methylphenidate hydrochloride 60 mg (modified release)	Oral	Ritalin LA Rubifen LA
Methylphenidate	GRP-27209	Capsule containing methylphenidate hydrochloride 30 mg (modified release)	Oral	Ritalin LA Rubifen LA
Methylphenidate	GRP-27210	Capsule containing methylphenidate hydrochloride 10 mg (modified release)	Oral	Ritalin LA Rubifen LA
Methylphenidate	GRP-27215	Capsule containing methylphenidate hydrochloride 20 mg (modified release)	Oral	Ritalin LA Rubifen LA

[202] Schedule 5, after entry for Methylphenidate in the form Tablet containing methylphenidate hydrochloride 18 mg (extended release) Concerta (Switzerland) (S19A)

insert:

Methylphenidate	GRP-30065	Capsule containing methylphenidate hydrochloride 60 mg (modified release)	Oral	Ritalin LA Rubifen LA
Methylphenidate	GRP-30065	Capsule containing methylphenidate hydrochloride 60 mg (modified release) (s19A)	Oral	Methylphenidate Orifarm 60 mg (Denmark)
Methylphenidate	GRP-30077	Capsule containing methylphenidate hydrochloride 10 mg (modified release)	Oral	Ritalin LA Rubifen LA
Methylphenidate	GRP-30077	Capsule containing methylphenidate hydrochloride 10 mg (modified release) (s19A)	Oral	Methylphenidate Orifarm 10 mg (Sweden)
Methylphenidate	GRP-30099	Capsule containing methylphenidate hydrochloride 20 mg (modified release)	Oral	Ritalin LA Rubifen LA
Methylphenidate	GRP-30099	Capsule containing methylphenidate hydrochloride 20 mg (modified release) (s19A)	Oral	Methylphenidate Orifarm 20 mg (Sweden)
Methylphenidate	GRP-30100	Capsule containing methylphenidate hydrochloride 30 mg (modified release)	Oral	Ritalin LA Rubifen LA
Methylphenidate	GRP-30100	Capsule containing methylphenidate hydrochloride 30 mg (modified release) (s19A)	Oral	Methylphenidate Orifarm 30 mg (Sweden)

[203] Schedule 5, entry for Montelukast *[GRP-19572]*

omit from the column headed "Brand": Montelukast Mylan

[204] Schedule 5, entries for Morphine

omit:

Morphine	GRP-19707	Tablet containing morphine sulfate pentahydrate 60 mg (controlled release)	Oral	MORPHINE MR APOTEX MS Contin

[205] Schedule 5, entries for Morphine

omit:

Morphine	GRP-19730	Tablet containing morphine sulfate pentahydrate 100 mg (controlled release)	Oral	MORPHINE MR APOTEX MS Contin

[206] Schedule 5, entries for Morphine

omit:

Morphine	GRP-19885	Tablet containing morphine sulfate pentahydrate 10 mg (controlled release)	Oral	MORPHINE MR APOTEX MS Contin

[207] Schedule 5, entries for Morphine

omit:

Morphine	GRP-19923	Tablet containing morphine sulfate pentahydrate 30 mg (controlled release)	Oral	MORPHINE MR APOTEX MS Contin

[208] Schedule 5, entries for Morphine

omit:

Morphine	GRP-28109	Oral solution containing morphine sulfate 2 mg per mL in 100 mL bottle, 1 mL (S19A)	Oral	Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL)

[209] Schedule 5, entries for Morphine

omit:

Morphine	GRP-28109	Oral solution containing morphine sulfate 2 mg per mL in 500 mL bottle, 1 mL (S19A)	Oral	Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL)

[210] Schedule 5, entries for Morphine

omit:

Morphine	GRP-28497	Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL	Oral	Ordine 10

[211] Schedule 5, entries for Morphine

omit:

Morphine	GRP-28497	Oral solution containing morhine hydrochloride trihydrate 10 mg per mL, 01 mL (S19A)	Oral	Morphini HCl Streuli

[212] Schedule 5, entry for Mycophenolic acid *[GRP-20011]*

omit from the column headed "Brand": MycoCept

[213] Schedule 5, entry for Olmesartan with amlodipine *[GRP-21156]*

omit from the column headed "Brand": Olmesartan/Amlodipine 20/5 APOTEX

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

omit from the column headed "Brand": Pemzo

[215] Schedule 5, entry for Ondansetron *[GRP-19791]*

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

[216] Schedule 5, entry for Ondansetron *[GRP-19626]*

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

[217] Schedule 5, entry for Paroxetine

substitute:

Paroxetine	GRP-15790	Tablet 20 mg (as hydrochloride)	Oral	APX-Paroxetine Aropax Blooms The Chemist Paroxetine Extine 20 Paroxetine GH Paroxetine Sandoz PAROXETINE-WGR Paxtine

[218] Schedule 5, after entry for Pegfilgrastim

insert:

Peginterferon alfa-2a	GRP-30057	Injection 135 micrograms in 0.5 mL single use pre-filled syringe	Injection	Pegasys
Peginterferon alfa-2a	GRP-30057	Injection 135 micrograms in 0.5 mL single use pre-filled syringe (s19A)	Injection	Pegasys (Ireland)
Peginterferon alfa-2a	GRP-30076	Injection 180 micrograms in 0.5 mL single use pre-filled syringe	Injection	Pegasys
Peginterferon alfa-2a	GRP-30076	Injection 180 micrograms in 0.5 mL single use pre-filled syringe (s19A)	Injection	Pegasys (Ireland)

[219] Schedule 5, entry for Perindopril in the form Tablet containing perindopril erbumine 4 mg

omit from the column headed "Brand": Blooms the Chemist Perindopril

[220] Schedule 5, entry for Perindopril in the form Tablet containing perindopril erbumine 8 mg

omit from the column headed "Brand": Blooms the Chemist Perindopril

[221] Schedule 5, entry for Perindopril in the form Tablet containing perindopril erbumine 2 mg

omit from the column headed "Brand": Blooms the Chemist Perindopril

[222] Schedule 5, entry for Pioglitazone *[GRP-19814]*

omit from the column headed "Brand": APOTEX-Pioglitazone

[223] Schedule 5, entry for Pramipexole *[GRP-20529]*

omit from the column headed "Brand": APO-Pramipexole ER

[224] Schedule 5, entry for Pramipexole *[GRP-20530]*

omit from the column headed "Brand": APO-Pramipexole ER

[225] Schedule 5, entry for Pramipexole *[GRP-20531]*

omit from the column headed "Brand": APO-Pramipexole ER

[226] Schedule 5, entry for Pramipexole *[GRP-20532]*

omit from the column headed "Brand": APO-Pramipexole ER

[227] Schedule 5, entry for Pramipexole *[GRP-20533]*

omit from the column headed "Brand": APO-Pramipexole ER

[228] Schedule 5, entry for Pramipexole *[GRP-20534]*

omit from the column headed "Brand": APO-Pramipexole ER

[229] Schedule 5, entry for Pramipexole *[GRP-20535]*

omit from the column headed "Brand": APO-Pramipexole ER

[230] Schedule 5, entries for Prazosin

omit:

Prazosin	GRP-19831	Tablet 2 mg (as hydrochloride)	Oral	APO-Prazosin Minipress

[231] Schedule 5, after entry for Prazosin in the form Tablet 1 mg (as hydrochloride)

insert:

Prazosin	GRP-30056	Capsule 2 mg (as hydrochloride) (S19A)	Oral	Prazosin Hydrochloride Capsules, USP 2 mg (Novitium Pharma, USA)
Prazosin	GRP-30056	Tablet 2 mg (as hydrochloride)	Oral	APO-Prazosin Minipress

[232] Schedule 5, entry for Pregabalin *[GRP-21628]*

omit from the column headed "Brand": Blooms The Chemist Pregabalin

[233] Schedule 5, entry for Pregabalin *[GRP-21640]*

omit from the column headed "Brand": Blooms The Chemist Pregabalin

[234] Schedule 5, entry for Pregabalin *[GRP-21642]*

omit from the column headed "Brand": Blooms The Chemist Pregabalin

[235] Schedule 5, entries for Rivaroxaban

omit:

Rivaroxaban	GRP-29164	Tablet 20 mg	Oral	APO-Rivaroxaban ARX-Rivaroxaban 20 iXarola Relaban Rivarelto Rivaroxaban Dr.Reddy's Rivaroxaban Lupin Rivaroxaban Sandoz Rivaroxaban-Teva RIVAXIB Rivoxa Xarelto

[236] Schedule 5, entries for Rivaroxaban

omit:

Rivaroxaban	GRP-29173	Tablet 15 mg	Oral	APO-Rivaroxaban ARX-Rivaroxaban 15 iXarola Relaban

				Rivarelto Rivaroxaban Dr.Reddy's Rivaroxaban Lupin Rivaroxaban Sandoz Rivaroxaban-Teva RIVAXIB Rivoxa Xarelto

[237] Schedule 5, after entry for Rivaroxaban *[GRP-29169]*

insert:

Rivaroxaban	GRP-30058	Capsule 15 mg	Oral	Relaban
Rivaroxaban	GRP-30058	Tablet 15 mg	Oral	APO-Rivaroxaban ARX-Rivaroxaban 15 iXarola Rivarelto Rivaroxaban Dr.Reddy's Rivaroxaban Lupin Rivaroxaban Sandoz Rivaroxaban-Teva RIVAXIB Rivoxa Xarelto
Rivaroxaban	GRP-30067	Capsule 20 mg	Oral	Relaban
Rivaroxaban	GRP-30067	Tablet 20 mg	Oral	APO-Rivaroxaban ARX-Rivaroxaban 20 iXarola Rivarelto Rivaroxaban Dr.Reddy's Rivaroxaban Lupin Rivaroxaban Sandoz Rivaroxaban-Teva RIVAXIB Rivoxa Xarelto

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

insert in the column headed "Brand" after entry for the brand "RIXALT": Rizatriptan-Au

[239] Schedule 5, entry for Rosuvastatin *[GRP-19569]*

omit from the column headed "Brand": Rosuvastatin APOTEX

[240] Schedule 5, entry for Roxithromycin *[GRP-20052]*

omit from the column headed "Brand": APO-Roxithromycin

[241] Schedule 5, entry for Roxithromycin *[GRP-20144]*

omit from the column headed "Brand": APO-Roxithromycin

[242] Schedule 5, entry for Valaciclovir

substitute:

Valaciclovir	GRP-19634	Tablet 500 mg (as hydrochloride)	Oral	APX-Valaciclovir Shilova 500 Vaclovir Valaciclovir RBX Valaciclovir Sandoz Valaciclovir SZ VALACICLOVIR-WGR Valtrex Zelitrex