PB 112 of 2023

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 12)

National Health Act 1953

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

Dated 30 November 2023

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

Contents

1 Name

(1) This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 12)*.

(2) This Instrument may also be cited as PB 112 of 2023.

2 Commencement

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

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. *The whole of this instrument*	*1 December 2023*	*1 December 2023*

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Listing of Pharmaceutical Benefits) Instrument 2012 (PB 71 of 2012)

[1] Schedule 1, Part 1, entry for Adalimumab

substitute:

Adalimumab	Injection 20 mg in 0.2 mL pre-filled syringe	Injection	Humira	VE	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
					MP	C9715 C11713 C11715 C11716 C11717 C11761 C11767 C11852 C11853 C11854 C11855 C11903 C11966	P11713	2	0	2	
					MP	C9715 C11713 C11715 C11716 C11717 C11761 C11767 C11852 C11853 C11854 C11855 C11903 C11966	P9715 P11715 P11716 P11761 P11852 P11854 P11855	2	3	2	
					MP	C9715 C11713 C11715 C11716 C11717 C11761 C11767 C11852 C11853 C11854 C11855 C11903 C11966	P11717 P11767 P11853 P11903 P11966	2	5	2	
					MP	C14107 C14136		2	5	2	C(100)
	Injection 20 mg in 0.4 mL pre-filled syringe	Injection	Amgevita	XT	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	C(100)
					MP	C9715 C11579 C11713 C11715 C11716 C11717 C11718 C11761	P11713	2	0	1	

					C11767 C11852 C11853 C11854 C11855 C11903 C11966					
				MP	C9715 C11579 C11713 C11715 C11716 C11717 C11718 C11761 C11767 C11852 C11853 C11854 C11855 C11903 C11966	P9715 P11715 P11716 P11761 P11852 P11854 P11855	2	3	1	
				MP	C9715 C11579 C11713 C11715 C11716 C11717 C11718 C11761 C11767 C11852 C11853 C11854 C11855 C11903 C11966	P11579 P11717 P11718 P11767 P11853 P11903 P11966	2	5	1	
				MP	C14107 C14136		2	5	1	C(100)
Injection 40 mg in 0.4 mL pre-filled pen	Injection	Humira	VE	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
		Yuflyma	EW	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
		Humira	VE	MP	C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101	P11713	2	0	2	

			C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730				
Yuflyma	EW	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157	P11713	2	0	2

				C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Humira	VE	MP	C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2	

				C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730				
	Yuflyma	EW	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2

				C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Humira	VE	MP	C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14498 P14655 P14662 P14670	2	3	2

				C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730				
	Yuflyma	EW	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673	2	3	2

				C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Humira	VE	MP	C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670	P11107 P12155 P12212 P13556 P13612 P14377 P14378	2	4	2

			C14713 C14730					
	Yuflyma	EW MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683	P11107 P12155 P12212 P13556 P13612 P14377 P14378	2	4	2

				C14701 C14713 C14730					
	Humira	VE	MP	C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730	P11704 P11711 P11717 P11767 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14656 P14713 P14730	2	5	2	
			MP	C14107 C14136		2	5	2	C(100)
	Yuflyma	EW	MP	C9064 C9386 C9715 C11107 C11523 C11524	P11523 P11524 P11579 P11604 P11606 P11631	2	5	2	

		C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730	P11635 P11704 P11711 P11717 P11718 P11767 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730				
	MP	C14107 C14136		2	5	2	C(100)

	Humira	VE	MP	C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730	P12273	4	2	2
	Yuflyma	EW	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713	P12273	4	2	2

				C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Humira	VE	MP	C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767	P12272 P12315	4	5	2

				C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730				
	Yuflyma	EW	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867	P11529 P12272 P12315	4	5	2

				C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Humira	VE	MP	C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336 P13602 P13609	6	0	2	

				C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730				
	Yuflyma	EW	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336 P13602 P13609	6	0	2	

					C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730					
Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Humira	VE	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
		Yuflyma	EW	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
		Humira	VE	MP	C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148	P11713	2	0	2	

				C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730				
	Yuflyma	EW	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240	P11713	2	0	2

				C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Humira	VE	MP	C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2

			C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730					
	Yuflyma	EW	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2

				C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Humira	VE	MP	C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14498 P14655 P14662 P14670	2	3	2
	Yuflyma	EW	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483	2	3	2

				C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730	P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673			
	Humira	VE	MP	C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767	P11107 P12155 P12212 P13556 P13612 P14377 P14378	2	4	2

				C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730				
	Yuflyma	EW	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101	P11107 P12155 P12212 P13556 P13612 P14377 P14378	2	4	2

				C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Humira	VE	MP	C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194	P11704 P11711 P11717 P11767 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14656 P14713 P14730	2	5	2	

				C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730				
			MP	C14107 C14136		2	5	2	C(100)
	Yuflyma	EW	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609	P11523 P11524 P11579 P11604 P11606 P11631 P11635 P11704 P11711 P11717 P11718 P11767 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730	2	5	2	

				C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
			MP	C14107 C14136		2	5	2	C(100)
	Humira	VE	MP	C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	6	0	2	

				C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730				
	Yuflyma	EW	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	6	0	2

					C14670 C14672 C14673 C14683 C14701 C14713 C14730				
Injection 40 mg in 0.8 mL pre-filled pen	Injection	Amgevita	XT	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
		Hadlima	RF	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
		Hyrimoz	SZ	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
		Idacio	PK	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
		Amgevita	XT	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275	P11713	2	0	2	

				C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hadlima	RF	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272	P11713	2	0	2

				C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hyrimoz	SZ	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228	P11713	2	0	2

				C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Idacio	PK	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212	P11713	2	0	2	

				C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Amgevita	XT	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2	

				C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hadlima	RF	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2	

				C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hyrimoz	SZ	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2	

				C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Idacio	PK	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2	

				C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Amgevita	XT	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673	2	3	2	

				C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hadlima	RF	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673	2	3	2

				C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hyrimoz	SZ	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673	2	3	2	

				C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Idacio	PK	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673	2	3	2	

				C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Amgevita	XT	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867	P11107 P12155 P12212 P13556 P13612 P14377 P14378	2	4	2

				C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hadlima	RF	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861	P11107 P12155 P12212 P13556 P13612 P14377 P14378	2	4	2	

				C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hyrimoz	SZ	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854	P11107 P12155 P12212 P13556 P13612 P14377 P14378	2	4	2

				C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Idacio	PK	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852	P11107 P12155 P12212 P13556 P13612 P14377 P14378	2	4	2

				C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Amgevita	XT	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761	P11523 P11524 P11579 P11604 P11606 P11631 P11635 P11704 P11711 P11717 P11718 P11767 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156	2	5	2

				C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730	P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730				
			MP	C14107 C14136		2	5	2	C(100)
	Hadlima	RF	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713	P11523 P11524 P11579 P11604 P11606 P11631 P11635 P11704 P11711 P11717 P11718 P11767 P11853 P11865 P11867 P11903	2	5	2	

				C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730	P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730				
			MP	C14107 C14136		2	5	2	C(100)
	Hyrimoz	SZ	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606	P11523 P11524 P11579 P11604 P11606 P11631 P11635 P11704 P11711 P11717	2	5	2	

				C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730	P11718 P11767 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730				
			MP	C14107 C14136		2	5	2	C(100)
	Idacio	PK	MP	C9064 C9386 C9715 C11107	P11523 P11524 P11579 P11604	2	5	2	

		C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730	P11606 P11631 P11635 P11704 P11711 P11717 P11718 P11767 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730				
	MP	C14107 C14136		2	5	2	C(100)

	Amgevita	XT	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713	P12273	4	2	2

				C14730				
	Hadlima	RF	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683	P12273	4	2	2

				C14701 C14713 C14730				
	Hyrimoz	SZ	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672	P12273	4	2	2

				C14673 C14683 C14701 C14713 C14730				
	Idacio	PK	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662	P12273	4	2	2

				C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Amgevita	XT	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655	P11529 P12272 P12315	4	5	2

				C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hadlima	RF	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568	P11529 P12272 P12315	4	5	2

				C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hyrimoz	SZ	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507	P11529 P12272 P12315	4	5	2

				C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Idacio	PK	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498	P11529 P12272 P12315	4	5	2

				C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Amgevita	XT	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336 P13602 P13609	6	0	2

				C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hadlima	RF	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336 P13602 P13609	6	0	2

				C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hyrimoz	SZ	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336 P13602 P13609	6	0	2

				C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Idacio	PK	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336 P13602 P13609	6	0	2

					C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730					
Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Amgevita	XT	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
		Hadlima	RF	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
		Hyrimoz	SZ	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
		Idacio	PK	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
		Amgevita	XT	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148	P11713	2	0	2	

				C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hadlima	RF	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158	P11713	2	0	2

				C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hyrimoz	SZ	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194	P11713	2	0	2

				C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Idacio	PK	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240	P11713	2	0	2

				C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Amgevita	XT	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2	

				C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hadlima	RF	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2

				C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hyrimoz	SZ	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2

				C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Idacio	PK	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2

				C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Amgevita	XT	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673	2	3	2

				C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hadlima	RF	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673	2	3	2

				C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hyrimoz	SZ	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673	2	3	2

				C14701 C14713 C14730				
	Idacio	PK	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673	2	3	2

	Amgevita	XT	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730	P11107 P12155 P12212 P13556 P13612 P14377 P14378	2	4	2
	Hadlima	RF	MP	C9064 C9386 C9715 C11107	P11107 P12155 P12212 P13556	2	4	2

				C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730	P13612 P14377 P14378			
	Hyrimoz	SZ	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604	P11107 P12155 P12212 P13556 P13612 P14377 P14378	2	4	2

			C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Idacio	PK MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704	P11107 P12155 P12212 P13556 P13612 P14377 P14378	2	4	2	

				C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Amgevita	XT	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715	P11523 P11524 P11579 P11604 P11606 P11631 P11635 P11704 P11711 P11717 P11718 P11767 P11853 P11865 P11867 P11903	2	5	2

				C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730	P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730				
			MP	C14107 C14136		2	5	2	C(100)
	Hadlima	RF	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715	P11523 P11524 P11579 P11604 P11606 P11631 P11635 P11704 P11711 P11717 P11718 P11767 P11853 P11865 P11867 P11903	2	5	2	

				C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730	P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730				
			MP	C14107 C14136		2	5	2	C(100)
	Hyrimoz	SZ	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715	P11523 P11524 P11579 P11604 P11606 P11631 P11635 P11704 P11711 P11717 P11718 P11767 P11853 P11865 P11867 P11903	2	5	2	

				C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730	P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730				
			MP	C14107 C14136		2	5	2	C(100)
	Idacio	PK	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715	P11523 P11524 P11579 P11604 P11606 P11631 P11635 P11704 P11711 P11717 P11718 P11767 P11853 P11865 P11867 P11903	2	5	2	

				C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730	P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730				
			MP	C14107 C14136		2	5	2	C(100)
	Amgevita	XT	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	6	0	2	

				C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hadlima	RF	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	6	0	2

				C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Hyrimoz	SZ	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	6	0	2	

				C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
	Idacio	PK	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	6	0	2	

					C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730				
Injection 80 mg in 0.8 mL pre-filled pen	Injection	Humira	VE	MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12155 C12212 C12229 C12273 C12275 C12278 C12306 C14398 C14399	P12103 P12105 P12155 P12212 P14398 P14399	1	0	1
				MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854	P12273	2	2	1

					C11855 C12103 C12105 C12152 C12155 C12212 C12229 C12273 C12275 C12278 C12306 C14398 C14399				
				MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12155 C12212 C12229 C12273 C12275 C12278 C12306 C14398 C14399	P12306	2	5	1
				MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12155 C12212 C12229 C12273 C12275 C12278 C12306 C14398 C14399	P11715 P11716 P11759 P11761 P11762 P11763 P11852 P11854 P11855 P12152 P12229 P12275 P12278	3	0	1
Injection 80 mg in 0.8 mL pre-filled syringe	Injection	Humira	VE	MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12155 C12212 C12229 C12273 C12275 C12278 C12306 C14398 C14399	P12103 P12105 P12155 P12212 P14398 P14399	1	0	1

				MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12155 C12212 C12229 C12273 C12275 C12278 C12306 C14398 C14399	P12273	2	2	1
				MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12155 C12212 C12229 C12273 C12275 C12278 C12306 C14398 C14399	P12306	2	5	1
				MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12155 C12212 C12229 C12273 C12275 C12278 C12306 C14398 C14399	P11715 P11716 P11759 P11761 P11762 P11763 P11852 P11854 P11855 P12152 P12229 P12275 P12278	3	0	1

[2] Schedule 1, Part 1, after entry for Adefovir in the form Tablet containing adefovir dipivoxil 10 mg

insert:

	Tablet containing adefovir dipivoxil 10 mg (S19A)	Oral	Adefovir Dipivoxil Tablets 10 mg (SigmaPharm Laboratories)	XW	MP NP	C4490 C4510	60	5	30	D(100)

[3] **Schedule 1, Part 1, entry for Alendronic acid with colecalciferol in the form Tablet 70 mg (as alendronate sodium) with 70 micrograms colecalciferol**

(a) *omit:*

	a	Alendronate Plus D3 Sandoz	SZ	MP NP	C6307 C6315 C6320	4	5	4

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

[4] **Schedule 1, Part 1, entry for Alendronic acid with colecalciferol in the form Tablet 70 mg (as alendronate sodium) with 140 micrograms colecalciferol**

(a) *omit:*

	a	Alendronate Plus D3 Sandoz	SZ	MP NP	C6306 C6319 C6325	4	5	4

(b) *omit from the column headed "Schedule Equivalent" for the brand "Fosamax Plus 70 mg/140 mcg":* **a**

[5] **Schedule 1, Part 1, entry for Amisulpride in the form Tablet 400 mg**

omit:

	a	Amisulpride 400 Winthrop	WA	MP NP	C4246	60	5	60

[6] **Schedule 1, Part 1, entry for Amitriptyline in the form Tablet containing amitriptyline hydrochloride 25 mg**

omit:

	a	Amitriptyline Alphapharm 25	MQ	MP NP		50	2	50

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

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

	a	Blooms The Chemist Amoxicillin	BG	MP NP MW PDP		20	0	20

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

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

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

[9] Schedule 1, Part 1, entry for Amoxicillin in the form Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL

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

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

omit:

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

[11] Schedule 1, Part 1, entry for Amoxicillin with clavulanic acid in the form Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *[Maximum Quantity: 10; Number of Repeats: 0]*

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

		Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125	BG	MP NP	C5832 C5893 C10413	P5832 P5893	10	0	10
				PDP	C5833 C5894		10	0	10

[12] Schedule 1, Part 1, entry for Amoxicillin with clavulanic acid in the form Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *[Maximum Quantity: 20; Number of Repeats: 0]*

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

		Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125	BG	MP NP	C5832 C5893 C10413	P10413	20	0	10

[13] Schedule 1, Part 1, entry for Bimekizumab in the form Injection 160 mg in 1 mL single use pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 2]*

(a) *omit from the column headed "Circumstances":* **C14438**

(b) *insert in numerical order in the column headed "Circumstances":* **C14726**

(c) *omit from the column headed "Purposes":* **P14438**

(d) *insert in numerical order in the column headed "Purposes":* **P14726**

[14] Schedule 1, Part 1, entry for Bimekizumab in the form Injection 160 mg in 1 mL single use pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 4]*

(a) *omit from the column headed "Circumstances":* **C14438**

(b) *insert in numerical order in the column headed "Circumstances":* **C14726**

[15] Schedule 1, Part 1, entry for Buprenorphine in the form Transdermal patch 5 mg

substitute:

Transdermal patch 5 mg	Transdermal	a	B-Patch	IU	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		a	B-Patch	IU	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
		a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2

[16] Schedule 1, Part 1, entry for Buprenorphine in the form Transdermal patch 10 mg

substitute:

Transdermal patch 10 mg	Transdermal	a	B-Patch	IU	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		a	B-Patch	IU	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
		a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2

[17] Schedule 1, Part 1, entry for Buprenorphine in the form Transdermal patch 15 mg

substitute:

Transdermal patch 15 mg	Transdermal	a	B-Patch	IU	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		a	B-Patch	IU	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
		a	Bupredermal	TX	MP NP	C10748 C10752	P11753	4	0	2

							C10755 C11753				
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	

[18] Schedule 1, Part 1, entry for Buprenorphine in the form Transdermal patch 20 mg

substitute:

Transdermal patch 20 mg	Transdermal	a	B-Patch	IU	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		a	B-Patch	IU	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
		a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	

[19] Schedule 1, Part 1, entry for Carboplatin

omit:

			DBL Carboplatin	PF	MP			See Note 3	See Note 3	1	D(100)

[20] Schedule 1, Part 1, entry for Cefepime in the form Powder for injection 2 g (as hydrochloride)

omit:

	a	Cefepime-AFT	AE	MP NP	C5842		10	0	1

[21] Schedule 1, Part 1, entry for Certolizumab pegol

substitute:

Certolizumab pegol	Injection 200 mg in 1 mL single use pre-filled syringe	Injection	Cimzia	UC	MP	C9063 C9073 C9074 C9105 C9183 C9185 C9431 C9625 C10431 C10459 C10513 C11386 C12392 C14191 C14493 C14499 C14507 C14542 C14571 C14591 C14622 C14659 C14686 C14692 C14714	P10459 P12392	2	0	2
					MP	C9063 C9073 C9074 C9105 C9183 C9185 C9431 C9625 C10431 C10459 C10513 C11386 C12392 C14191 C14493 C14499 C14507 C14542 C14571 C14591 C14622 C14659 C14686 C14692 C14714	P9185 P9625 P14542	2	2	2
					MP	C9063 C9073 C9074 C9105 C9183 C9185 C9431 C9625 C10431 C10459 C10513 C11386 C12392 C14191	P9063 P9105 P9431 P10431 P14493 P14499 P14507 P14692	2	5	2

					C14493 C14499 C14507 C14542 C14571 C14591 C14622 C14659 C14686 C14692 C14714				
				MP	C9063 C9073 C9074 C9105 C9183 C9185 C9431 C9625 C10431 C10459 C10513 C11386 C12392 C14191 C14493 C14499 C14507 C14542 C14571 C14591 C14622 C14659 C14686 C14692 C14714	P9073 P9074 P9183 P10513 P11386 P14191 P14571 P14591 P14622 P14659 P14686 P14714	6	0	2
Solution for injection 200 mg in 1 mL pre-filled pen	Injection	Cimzia	UC	MP	C9063 C9073 C9074 C9105 C9183 C9185 C9431 C9625 C10431 C10459 C10513 C11386 C12392 C14191 C14493 C14499 C14507 C14542 C14571 C14591 C14622 C14659 C14686 C14692 C14714	P10459 P12392	2	0	2
				MP	C9063 C9073 C9074 C9105 C9183 C9185 C9431 C9625 C10431 C10459 C10513 C11386 C12392 C14191 C14493 C14499 C14507 C14542	P9185 P9625 P14542	2	2	2

		C14571 C14591 C14622 C14659 C14686 C14692 C14714				
	MP	C9063 C9073 C9074 C9105 C9183 C9185 C9431 C9625 C10431 C10459 C10513 C11386 C12392 C14191 C14493 C14499 C14507 C14542 C14571 C14591 C14622 C14659 C14686 C14692 C14714	P9063 P9105 P9431 P10431 P14493 P14499 P14507 P14692	2	5	2
	MP	C9063 C9073 C9074 C9105 C9183 C9185 C9431 C9625 C10431 C10459 C10513 C11386 C12392 C14191 C14493 C14499 C14507 C14542 C14571 C14591 C14622 C14659 C14686 C14692 C14714	P9073 P9074 P9183 P10513 P11386 P14191 P14571 P14591 P14622 P14659 P14686 P14714	6	0	2

[22] Schedule 1, Part 1, entry for Clopidogrel in the form Tablet 75 mg (as hydrogen sulfate) *[Maximum Quantity: 28; Number of Repeats: 5]*

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

Blooms Clopidogrel BG	MP NP			28	5	28

[23] Schedule 1, Part 1, entry for Clopidogrel in the form Tablet 75 mg (as hydrogen sulfate) *[Maximum Quantity: 56; Number of Repeats: 5]*

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

Blooms Clopidogrel BG	MP NP		P14238	56	5	28

[24] Schedule 1, Part 1, entry for Colestyramine

omit:

	Sachet containing 4 g oral powder (s19A)	Oral		JAMP-Cholestyramine	DZ	MP NP			100	5	30
						MP		P6429	100	11	30

[25] Schedule 1, Part 1, entry for Cyclophosphamide in each of the forms: Powder for injection 500 mg (anhydrous); and Powder for injection 1 g (anhydrous)

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

				CYCLOPHOSPHAMIDE-REACH	RQ	MP			See Note 3	See Note 3	1 PB(100)

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

substitute:

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

							C14308				
		a	PHARMACOR DABIGATRAN	CR	MP NP	C4269 C4369 C4381 C4402 C14308	P4369	20	1	10	
		a	Pradaxa	BY	MP NP	C4269 C4369 C4381 C4402 C14308	P4369	20	1	10	
		a	Dabigatran Sandoz	SZ	MP NP	C4269 C4402 C14308	P4402	60	0	60	
		a	PHARMACOR DABIGATRAN	CR	MP NP	C4269 C4369 C4381 C4402 C14308	P4402	60	0	60	
		a	Pradaxa	BY	MP NP	C4269 C4369 C4381 C4402 C14308	P4402	60	0	60	
		a	Dabigatran Sandoz	SZ	MP NP	C4269 C4402 C14308	P4269	60	5	60	
		a	PHARMACOR DABIGATRAN	CR	MP NP	C4269 C4369 C4381 C4402 C14308	P4269	60	5	60	
		a	Pradaxa	BY	MP NP	C4269 C4369 C4381 C4402 C14308	P4269	60	5	60	
		a	Dabigatran Sandoz	SZ	MP NP	C4269 C4402 C14308	P14308	120	5	60	
		a	PHARMACOR DABIGATRAN	CR	MP NP	C4269 C4369 C4381 C4402 C14308	P14308	120	5	60	
		a	Pradaxa	BY	MP NP	C4269 C4369 C4381 C4402 C14308	P14308	120	5	60	
Capsule 150 mg (as mesilate)	Oral	a	Dabigatran Sandoz	SZ	MP NP	C4269 C14308	P4269	60	5	60	

			a	PHARMACOR DABIGATRAN	CR	MP NP	C4269 C14308	P4269	60	5	60	
			a	Pradaxa	BY	MP NP	C4269 C14308	P4269	60	5	60	
			a	Dabigatran Sandoz	SZ	MP NP	C4269 C14308	P14308	120	5	60	
			a	PHARMACOR DABIGATRAN	CR	MP NP	C4269 C14308	P14308	120	5	60	
			a	Pradaxa	BY	MP NP	C4269 C14308	P14308	120	5	60	

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

insert in numerical order in the column headed "Circumstances": **C14034**

[28] Schedule 1, Part 1, entry for Durvalumab in each of the forms: Solution concentrate for I.V. infusion 120 mg in 2.4 mL; and Solution concentrate for I.V. infusion 500 mg in 10 mL

omit from the column headed "Circumstances": **C10126 C12271** *substitute:* **C10126 C10206 C10509 C12271 C14708**

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

omit:

			a	ENTAC	LR	MP NP	C5037 C5044		60	5	30	D(100)

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

substitute:

Essential amino acids formula with vitamins and minerals	Sachets containing oral powder 12.5 g, 30 (EAA Supplement)	Oral	EAA Supplement	VF	MP NP	C4925 C4958		6	5	1	

[31] Schedule 1, Part 1, omit entry for Estradiol with dydrogesterone

[32] Schedule 1, Part 1, entry for Etanercept

substitute:

Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection	Enbrel	PF	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	C(100)

	MP	C7289 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9473 C11107 C12164 C12261 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703 C14713 C14715	P14508 P14509	2	1	1
	MP	C7289 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9473 C11107 C12164 C12261 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509	P9064 P9386 P9388 P9473 P11107 P12164 P12261 P13532 P13533 P13538 P13593 P13598 P13646 P13647 P14382 P14427 P14483 P14486 P14488 P14498 P14513 P14552 P14553 P14554 P14576 P14577 P14600 P14655 P14662 P14670 P14703	2	3	1

					C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703 C14713 C14715					
				MP	C7289 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9473 C11107 C12164 C12261 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703 C14713 C14715	P7289 P8839 P8842 P8873 P8879 P9081 P9123 P9140 P9162 P9377 P9380 P14493 P14499 P14507 P14656 P14713 P14715	2	5	1	
				MP	C14154 C14155		2	5	1	C(100)
Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Enbrel	PF	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	C(100)
				MP	C7289 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162	P14508 P14509	1	1	1	

				C9377 C9380 C9386 C9388 C9473 C11107 C12164 C12261 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703 C14713 C14715				
	Brenzys	RF	MP	C7289 C8839 C8842 C8873 C8879 C8887 C8955 C9064 C9081 C9123 C9140 C9156 C9162 C11107 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14581 C14582 C14603 C14629 C14655 C14656 C14662 C14670 C14671 C14673 C14683 C14701 C14703 C14713 C14715	P9064 P11107 P13532 P13533 P13538 P13593 P13598 P13646 P13647 P14382 P14427 P14483 P14486 P14488 P14498 P14581 P14582 P14603 P14655 P14662 P14670 P14671 P14673 P14703	1	3	1

	Enbrel	PF	MP	C7289 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9473 C11107 C12164 C12261 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703 C14713 C14715	P9064 P9386 P9388 P9473 P11107 P12164 P12261 P13532 P13533 P13538 P13593 P13598 P13646 P13647 P14382 P14427 P14483 P14486 P14488 P14498 P14513 P14552 P14553 P14554 P14576 P14577 P14600 P14655 P14662 P14670 P14703	1	3	1
	Brenzys	RF	MP	C7289 C8839 C8842 C8873 C8879 C8887 C8955 C9064 C9081 C9123 C9140 C9156 C9162 C11107 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14581 C14582 C14603 C14629 C14655 C14656	P7289 P8839 P8842 P8873 P8879 P8887 P8955 P9081 P9123 P9140 P9156 P9162 P14493 P14499 P14507 P14629 P14656 P14683 P14701 P14713 P14715	1	5	1

					C14662 C14670 C14671 C14673 C14683 C14701 C14703 C14713 C14715					
		Enbrel	PF	MP	C7289 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9473 C11107 C12164 C12261 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703 C14713 C14715	P7289 P8839 P8842 P8873 P8879 P9081 P9123 P9140 P9162 P9377 P9380 P14493 P14499 P14507 P14656 P14713 P14715	1	5	1	
				MP	C14154 C14155		1	5	1	C(100)
Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Enbrel	PF	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	C(100)
				MP	C7289 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388	P14508 P14509	1	1	1	

				C9473 C11107 C12164 C12261 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703 C14713 C14715				
	Brenzys	RF	MP	C7289 C8839 C8842 C8873 C8879 C8887 C8955 C9064 C9081 C9123 C9140 C9156 C9162 C11107 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14581 C14582 C14603 C14629 C14655 C14656 C14662 C14670 C14671 C14673 C14683 C14701 C14703 C14713 C14715	P9064 P11107 P13532 P13533 P13538 P13593 P13598 P13646 P13647 P14382 P14427 P14483 P14486 P14488 P14498 P14581 P14582 P14603 P14655 P14662 P14670 P14671 P14673 P14703	1	3	1	
	Enbrel	PF	MP	C7289 C8839	P9064 P9386	1	3	1	

				C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9473 C11107 C12164 C12261 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703 C14713 C14715	P9388 P9473 P11107 P12164 P12261 P13532 P13533 P13538 P13593 P13598 P13646 P13647 P14382 P14427 P14483 P14486 P14488 P14498 P14513 P14552 P14553 P14554 P14576 P14577 P14600 P14655 P14662 P14670 P14703			
	Brenzys	RF	MP	C7289 C8839 C8842 C8873 C8879 C8887 C8955 C9064 C9081 C9123 C9140 C9156 C9162 C11107 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14581 C14582 C14603 C14629 C14655 C14656 C14662 C14670	P7289 P8839 P8842 P8873 P8879 P8887 P8955 P9081 P9123 P9140 P9156 P9162 P14493 P14499 P14507 P14629 P14656 P14683 P14701 P14713 P14715	1	5	1

					C14671 C14673 C14683 C14701 C14703 C14713 C14715					
		Enbrel	PF	MP	C7289 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9473 C11107 C12164 C12261 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703 C14713 C14715	P7289 P8839 P8842 P8873 P8879 P9081 P9123 P9140 P9162 P9377 P9380 P14493 P14499 P14507 P14656 P14713 P14715	1	5	1	
				MP	C14154 C14155		1	5	1	C(100)

[33] Schedule 1, Part 1, entry for Fentanyl in the form Lozenge 600 micrograms (as citrate)

substitute:

	Lozenge 600 micrograms (as citrate)	Buccal	Actiq	TB	MP NP	C5904		60	0	30	

[34] Schedule 1, Part 1, entry for Fentanyl in the form Lozenge 800 micrograms (as citrate)

substitute:

	Lozenge 800 micrograms (as citrate)	Buccal	Actiq	TB	MP NP	C5904		60	0	30

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

omit:

	Lozenge 1200 micrograms (as citrate)	Buccal	Actiq	TB	MP NP	C5904 C5915	P5915	9	0	9
					MP NP	C5904 C5915	P5904	60	0	30
	Lozenge 1600 micrograms (as citrate)	Buccal	Actiq	TB	MP NP	C5904 C5915	P5915	9	0	9
					MP NP	C5904 C5915	P5904	60	0	30

[36] Schedule 1, Part 1, entry for Fentanyl in the form Tablet (orally disintegrating) 400 micrograms (as citrate)

substitute:

	Tablet (orally disintegrating) 400 micrograms (as citrate)	Buccal	Fentora	TB	MP NP	C6027		56	0	28

[37] Schedule 1, Part 1, entry for Fentanyl in the form Tablet (orally disintegrating) 600 micrograms (as citrate)

substitute:

	Tablet (orally disintegrating) 600 micrograms (as citrate)	Buccal	Fentora	TB	MP NP	C6027		56	0	28

[38] Schedule 1, Part 1, entry for Fentanyl in the form Tablet (orally disintegrating) 800 micrograms (as citrate)

substitute:

	Tablet (orally disintegrating) 800 micrograms (as citrate)	Buccal	Fentora	TB	MP NP	C6027		56	0	28

[39] Schedule 1, Part 1, entry for Filgrastim in the form Injection 300 micrograms in 0.5 mL single-use pre-filled syringe

omit:

			Neupogen	AN	MP	C6621 C6640 C6653 C6654		20	11	10 D(100)

						C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696				

[40] Schedule 1, Part 1, entry for Filgrastim

omit:

	Injection 300 micrograms in 1 mL	Injection	Neupogen	AN	MP	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696	20	11	10	D(100)

[41] Schedule 1, Part 1, entry for Filgrastim in the form Injection 480 micrograms in 0.5 mL single-use pre-filled syringe

omit:

			Neupogen	AN	MP	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696	20	11	10	D(100)

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

omit:

	Injection 480 micrograms in 1.6 mL	Injection	Neupogen	AN	MP	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822	20	11	10	D(100)

						C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696					

[43] Schedule 1, Part 1, entry for Fluorouracil in the form Injection 2500 mg in 50 mL

omit:

			DBL Fluorouracil Injection BP	PF	MP	C6266 C6297		See Note 3	See Note 3	1	D(100)

[44] Schedule 1, Part 1, entry for Golimumab

substitute:

Golimumab	Injection 50 mg in 0.5 mL single use pre-filled pen	Injection	Simponi	JC	MP	C9063 C9064 C9069 C9105 C9153 C9155 C9429 C9431 C10434 C10436 C10461 C10515 C11431 C14190 C14488 C14507 C14519 C14556 C14557 C14604 C14626 C14655 C14662 C14670 C14692	P9064 P9069 P9153 P9155 P9429 P10436 P10515 P11431 P14190 P14488 P14556 P14557 P14626 P14655 P14662 P14670	1	3	1
					MP	C9063 C9064 C9069 C9105 C9153 C9155 C9429 C9431 C10434 C10436 C10461 C10515 C11431 C14190 C14488 C14507 C14519 C14556 C14557 C14604 C14626 C14655 C14662 C14670 C14692	P9063 P9105 P9431 P10434 P10461 P14507 P14519 P14604 P14692	1	5	1

	Injection 50 mg in 0.5 mL single use pre-filled syringe	Injection	Simponi	JC	MP	C9063 C9064 C9069 C9105 C9153 C9155 C9429 C9431 C10434 C10436 C10461 C10515 C11431 C14190 C14488 C14507 C14519 C14556 C14557 C14604 C14626 C14655 C14662 C14670 C14692	P9064 P9069 P9153 P9155 P9429 P10436 P10515 P11431 P14190 P14488 P14556 P14557 P14626 P14655 P14662 P14670	1	3	1
					MP	C9063 C9064 C9069 C9105 C9153 C9155 C9429 C9431 C10434 C10436 C10461 C10515 C11431 C14190 C14488 C14507 C14519 C14556 C14557 C14604 C14626 C14655 C14662 C14670 C14692	P9063 P9105 P9431 P10434 P10461 P14507 P14519 P14604 P14692	1	5	1
	Injection 100 mg in 1 mL single use pre-filled pen	Injection	Simponi	JC	MP	C9651 C9705 C9745 C9770 C9822 C9823	P9745	1	1	1
					MP	C9651 C9705 C9745 C9770 C9822 C9823	P9651 P9770	1	5	1
					MP	C9651 C9705 C9745 C9770 C9822 C9823	P9705 P9822 P9823	3	0	1

[45] Schedule 1, Part 1, entry for Ibandronic acid

omit:

	Concentrated injection for I.V. infusion 6 mg (as ibandronate sodium monohydrate) in 6 mL	Injection	Bondronat	IX	MP	C5291 C9333		1	11	1	PB(100)

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

(a) *omit:*

			CIPLA IMATINIB ADULT	LR	MP	C9203 C9204 C9206 C9207 C9209 C9240 C9243 C9274 C9276 C9296 C12525 C12527 C12536 C12541 C12542 C12543	P9203 P9207 P12525 P12527 P12542 P12543	60	2	60	

(b) *omit:*

			CIPLA IMATINIB ADULT	LR	MP	C9203 C9204 C9206 C9207 C9209 C9240 C9243 C9274 C9276 C9296 C12525 C12527 C12536 C12541 C12542 C12543	P9204 P9206 P9209 P9240 P9243 P9274 P9276 P9296 P12536 P12541	60	5	60	

[47] Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate)

(a) *omit:*

			CIPLA IMATINIB ADULT	LR	MP	C9203 C9204 C9206 C9207 C9209 C9240 C9243 C9274 C9276 C9296 C12525 C12527 C12536 C12541 C12542 C12543	P9203 P9207 P12525 P12527 P12542 P12543	30	2	30	

(b) *omit:*

			CIPLA IMATINIB ADULT	LR	MP	C9203 C9204 C9206 C9207 C9209 C9240 C9243 C9274 C9276 C9296 C12525 C12527 C12536 C12541 C12542 C12543	P9204 P9206 P9209 P9240 P9243 P9274 P9276 P9296 P12536 P12541	30	5	30	

[48] Schedule 1, Part 1, entry for Infliximab

substitute:

Infliximab	Powder for I.V. infusion 100 mg	Injection	Inflectra	PF	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)
			Remicade	JC	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)
			Renflexis	OQ	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)
			Inflectra	PF	MP	C14504 C14505 C14585 C14638 C14683 C14689 C14701 C14723	P14504 P14505 P14585 P14638	3	2	1	PB(100)
			Remicade	JC	MP	C14504 C14505		3	2	1	PB(100)
			Renflexis	OQ	MP	C14504 C14505 C14585 C14638 C14683 C14689 C14701 C14723	P14504 P14505 P14585 P14638	3	2	1	PB(100)
			Inflectra	PF	MP	C14504 C14505 C14585 C14638 C14683 C14689 C14701 C14723	P14683 P14689 P14701 P14723	5	3	1	PB(100)
			Renflexis	OQ	MP	C14504 C14505 C14585 C14638 C14683 C14689	P14683 P14689 P14701 P14723	5	3	1	PB(100)

					C14701 C14723				
Solution for injection 120 mg in 1 mL pre-filled pen	Injection	Remsima SC	EW	MP	C11826 C11910 C13039 C13040 C13043 C13045 C13056 C13058 C13061 C13068 C13069 C13077 C13078 C13079 C13080 C13094 C13096 C13097 C13104 C14515 C14668	P13104	1	0	1
				MP	C11826 C11910 C13039 C13040 C13043 C13045 C13056 C13058 C13061 C13068 C13069 C13077 C13078 C13079 C13080 C13094 C13096 C13097 C13104 C14515 C14668	P13040 P13058 P13061 P13068 P13094 P13096	2	0	1
				MP	C11826 C11910 C13039 C13040 C13043 C13045 C13056 C13058 C13061 C13068 C13069 C13077 C13078 C13079 C13080 C13094 C13096 C13097 C13104 C14515 C14668	P13039 P13045 P13069 P13077 P13078 P13080 P13097	2	2	1
				MP	C11826 C11910 C13039 C13040 C13043 C13045 C13056 C13058 C13061 C13068 C13069 C13077	P11826 P11910 P13043 P13056 P13079 P14515 P14668	2	5	1

					C13078 C13079 C13080 C13094 C13096 C13097 C13104 C14515 C14668				
Solution for injection 120 mg in 1 mL pre-filled syringe	Injection	Remsima SC	EW	MP	C11826 C11910 C13039 C13040 C13043 C13045 C13056 C13058 C13061 C13068 C13069 C13077 C13078 C13079 C13080 C13094 C13096 C13097 C13104 C14515 C14668	P13104	1	0	1
				MP	C11826 C11910 C13039 C13040 C13043 C13045 C13056 C13058 C13061 C13068 C13069 C13077 C13078 C13079 C13080 C13094 C13096 C13097 C13104 C14515 C14668	P13040 P13058 P13061 P13068 P13094 P13096	2	0	1
				MP	C11826 C11910 C13039 C13040 C13043 C13045 C13056 C13058 C13061 C13068 C13069 C13077 C13078 C13079 C13080 C13094 C13096 C13097 C13104 C14515 C14668	P13039 P13045 P13069 P13077 P13078 P13080 P13097	2	2	1
				MP	C11826 C11910 C13039 C13040	P11826 P11910 P13043 P13056	2	5	1

						C13043 C13045 C13056 C13058 C13061 C13068 C13069 C13077 C13078 C13079 C13080 C13094 C13096 C13097 C13104 C14515 C14668	P13079 P14515 P14668			

[49] Schedule 1, Part 1, entry for Insulin neutral with insulin isophane

omit:

	Injections (human), cartridges, 50 units-50 units per mL, 3 mL, 5	Injection	Mixtard 50/50 Penfill 3 mL	NO	MP NP			5	1	1

[50] Schedule 1, Part 1, entry for Ixekizumab

substitute:

Ixekizumab	Injection 80 mg in 1 mL single dose pre-filled pen	Injection	Taltz	LY	MP	C6696 C8830 C8892 C9172 C9429 C9431 C11089 C11096 C11107 C11138 C11154 C11834 C11918 C11958 C11959 C11981 C14453 C14461 C14655 C14662 C14670 C14692	P9429 P14655 P14662 P14670	2	1	2
					MP	C6696 C8830 C8892 C9172 C9429 C9431 C11089 C11096 C11107 C11138 C11154 C11834 C11918 C11958 C11959 C11981 C14453 C14461 C14655 C14662 C14670 C14692	P6696 P8830 P8892 P9172 P9431 P11834 P11918 P11958 P11959 P11981 P14692	2	2	2

						MP	C6696 C8830 C8892 C9172 C9429 C9431 C11089 C11096 C11107 C11138 C11154 C11834 C11918 C11958 C11959 C11981 C14453 C14461 C14655 C14662 C14670 C14692	P11089 P11096 P11107 P11138 P11154 P14453 P14461	2	3	2	

[51] Schedule 1, Part 1, entry for Macrogol 3350

substitute:

Macrogol 3350	Powder for oral solution 510 g	Oral		OsmoLax	KY	MP	See Note 2	See Note 2	See Note 2	See Note 2	1	C(100)
						MP NP	C4171 C4173 C4177 C4179 C4180 C6170	P4171 P4173 P4177 P4179 P4180	1	5	1	
						MP NP	C4171 C4173 C4177 C4179 C4180 C6170	P6170	2	3	1	
	Sachets containing powder for oral solution 13.125 g with electrolytes, 30	Oral	a	APOHEALTH Macrogol with Electrolytes	GX	MP	See Note 2	See Note 2	See Note 2	See Note 2	1	C(100)
			a	APO-MACROGOL plus ELECTROLYTES	TX	MP	See Note 2	See Note 2	See Note 2	See Note 2	1	C(100)
			a	Chemists' Own Macrogol with Electrolytes	RW	MP	See Note 2	See Note 2	See Note 2	See Note 2	1	C(100)
			a	Macrovic	RF	MP	See Note 2	See Note 2	See Note 2	See Note 2	1	C(100)
			a	Molaxole	GO	MP	See Note 2	See Note 2	See Note 2	See Note 2	1	C(100)

a	Movicol	NE	MP	See Note 2	See Note 2	See Note 2	See Note 2	1	C(100)
a	APOHEALTH Macrogol with Electrolytes	GX	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P4576 P4577 P4580 P4596 P4601	1	5	1	
a	APO-MACROGOL plus ELECTROLYTES	TX	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P4576 P4577 P4580 P4596 P4601	1	5	1	
a	Chemists' Own Macrogol with Electrolytes	RW	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P4576 P4577 P4580 P4596 P4601	1	5	1	
a	Macrovic	RF	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P4576 P4577 P4580 P4596 P4601	1	5	1	
a	Molaxole	GO	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P4576 P4577 P4580 P4596 P4601	1	5	1	
a	Movicol	NE	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P4576 P4577 P4580 P4596 P4601	1	5	1	
a	APOHEALTH Macrogol with Electrolytes	GX	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P6171	2	3	1	
a	APO-MACROGOL plus ELECTROLYTES	TX	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P6171	2	3	1	
a	Chemists' Own Macrogol with Electrolytes	RW	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P6171	2	3	1	
a	Macrovic	RF	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P6171	2	3	1	
a	Molaxole	GO	MP NP	C4576 C4577	P6171	2	3	1	

						C4580 C4596 C4601 C6171				
		a	Movicol	NE	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P6171	2	3	1

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

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

			Meloxicam Viatris	AL	MP NP	C4907 C4962		30	3	30

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

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

		a	Blooms The Chemist Metformin 500 mg	BG	MP NP			100	5	100

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

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

		a	Blooms The Chemist Metformin 850 mg	BG	MP NP			60	5	60

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

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

		a	Blooms The Chemist Metformin 1000 mg	BG	MP NP			90	5	90

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

insert:

Oral solution containing morphine sulfate 2 mg per mL in 100 mL bottle, 1 mL (S19A)	Oral		Morphine Sulfate (Hikma) 10 mg/5 mL	DZ	MP NP	C10764 C10770 C10777 C11697	P10764 P10770 P10777	200	0	100

		(2 mg/mL)							
				PDP	C10859		200	0	100
				MP NP	C10764 C10770 C10777 C11697	P11697	1000	1	100
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	C10764 C10770 C10777 C11697	P10764 P10770 P10777	200	0	500
				PDP	C10859		200	0	500
				MP NP	C10764 C10770 C10777 C11697	P11697	2000	1	500

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

insert:

Oral solution containing morphine sulfate 10 mg per 5 mL in 100 mL bottle, 1 mL (S19A)	Oral	Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL	LM	MP NP	C10764 C10770 C10777 C11697	P10764 P10770 P10777	200	0	100
				PDP	C10859		200	0	100
				MP NP	C10764 C10770 C10777 C11697	P11697	1000	1	100
Oral solution containing morphine sulfate 10 mg per 5 mL in 300 mL bottle, 1 mL (S19A)	Oral	Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL	LM	MP NP	C10764 C10770 C10777 C11697	P10764 P10770 P10777	200	0	300
				PDP	C10859		200	0	300
				MP NP	C10764 C10770 C10777 C11697	P11697	2100	1	300

[58] Schedule 1, Part 1, entry for Moxonidine in the form Tablet 400 micrograms

(a) *omit:*

			a	Moxonidine MYL	AF	MP NP	C4944 C14289	P4944	30	5	30

(b) *omit:*

			a	Moxonidine MYL	AF	MP NP	C4944 C14289	P14289	60	5	30

[59] Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid

substitute:

	Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid	Oral	a	MYCOTEX	CR	MP			120	5	120
			a	Myfortic	NV	MP			120	5	120
			a	MYCOTEX	CR	MP		P4084 P4095 P9692 P9809	240 CN4084 CN4095 CN9692 CN9809	5 CN4084 CN4095 CN9692 CN9809	120
			a	Myfortic	NV	MP		P4084 P4095 P9692 P9809	240 CN4084 CN4095 CN9692 CN9809	5 CN4084 CN4095 CN9692 CN9809	120

[60] Schedule 1, Part 1, entry for Nevirapine in the form Tablet 200 mg

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

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

			a	Nevirapine Viatris	AL	MP NP	C4454 C4512		120	5	60	D(100)

[61] Schedule 1, Part 1, entry for Nicorandil in each of the forms: Tablets 10 mg, 60; and Tablets 20 mg, 60

(a) *omit:*

		a	Ikorel	SW	MP NP			1	5	1	

(b) *omit:*

		a	Ikorel	SW	MP NP	P14238		2	5	1	

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

(a) *omit from the column headed "Circumstances":* **C13888**

(b) *insert in numerical order in the column headed "Circumstances":* **C14676**

[63] Schedule 1, Part 1, entry for Octreotide in the form Injection 500 micrograms (as acetate) in 1 mL

omit:

		a	Octreotide MaxRx	GQ	MP	C6369 C6390 C8165 C9232 C9233 C9289		90	11	5	D(100)

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

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

			Zypine ODT	AF	MP NP	C5856 C5869		28	5	28	

[65] Schedule 1, Part 1, entry for Olanzapine in each of the forms: Tablet 10 mg (orally disintegrating); Tablet 15 mg (orally disintegrating); and Tablet 20 mg (orally disintegrating)

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

			Zypine ODT	AF	MP NP	C5856 C5869		28	5	28	

[66] Schedule 1, Part 1, entry for Olanzapine in each of the forms: Wafer 5 mg; Wafer 10 mg; Wafer 15 mg; and Wafer 20 mg

omit:

			Zypine ODT	AF	MP NP	C5856 C5869		28	5	28	

[67] Schedule 1, Part 1, entry for Olmesartan in the form Tablet containing olmesartan medoxomil 20 mg *[Maximum Quantity: 30; Number of Repeats: 5]*

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

			a	Blooms The Chemist Olmesartan	BG	MP NP			30	5	30

[68] Schedule 1, Part 1, entry for Olmesartan in the form Tablet containing olmesartan medoxomil 20 mg *[Maximum Quantity: 60; Number of Repeats: 5]*

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

			a	Blooms The Chemist Olmesartan	BG	MP NP		P14238	60	5	30

[69] Schedule 1, Part 1, entry for Olmesartan in the form Tablet containing olmesartan medoxomil 40 mg *[Maximum Quantity: 30; Number of Repeats: 5]*

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

			a	Blooms The Chemist Olmesartan	BG	MP NP			30	5	30

[70] Schedule 1, Part 1, entry for Olmesartan in the form Tablet containing olmesartan medoxomil 40 mg *[Maximum Quantity: 60; Number of Repeats: 5]*

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

			a	Blooms The Chemist Olmesartan	BG	MP NP		P14238	60	5	30

[71] Schedule 1, Part 1, entry for Olmesartan with amlodipine

substitute:

Olmesartan with amlodipine	Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate)	Oral	a	OLMEKAR	RW	MP NP	C4373 C14257	P4373	30	5	30

		a	Olmesartan/Amlodipine 20/5 APOTEX	TX	MP NP	C4373 C14257	P4373	30	5	30
		a	Olmesartan/Amlodipine - MYL 20/5	AF	MP NP	C4373 C14257	P4373	30	5	30
		a	Olmesartan/Amlodipine Sandoz	SZ	MP NP	C4373 C14257	P4373	30	5	30
		a	Pharmacor Olmesartan Amlodipine 20/5	CR	MP NP	C4373 C14257	P4373	30	5	30
		a	Sevikar 20/5	AL	MP NP	C4373 C14257	P4373	30	5	30
		a	OLMEKAR	RW	MP NP	C4373 C14257	P14257	60	5	30
		a	Olmesartan/Amlodipine 20/5 APOTEX	TX	MP NP	C4373 C14257	P14257	60	5	30
		a	Olmesartan/Amlodipine - MYL 20/5	AF	MP NP	C4373 C14257	P14257	60	5	30
		a	Olmesartan/Amlodipine Sandoz	SZ	MP NP	C4373 C14257	P14257	60	5	30
		a	Pharmacor Olmesartan Amlodipine 20/5	CR	MP NP	C4373 C14257	P14257	60	5	30
		a	Sevikar 20/5	AL	MP NP	C4373 C14257	P14257	60	5	30
Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate)	Oral	a	OLMEKAR	RW	MP NP	C4373		30	5	30
		a	Olmesartan/Amlodipine 40/5 APOTEX	TX	MP NP	C4373		30	5	30
		a	Olmesartan/Amlodipine - MYL 40/5	AF	MP NP	C4373		30	5	30
		a	Olmesartan/Amlodipine Sandoz	SZ	MP NP	C4373		30	5	30

			a	Pharmacor Olmesartan Amlodipine 40/5	CR	MP NP	C4373	30	5	30	
			a	Sevikar 40/5	AL	MP NP	C4373	30	5	30	
	Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate)	Oral	a	OLMEKAR	RW	MP NP	C4373	30	5	30	
			a	Olmesartan/Amlodipine 40/10 APOTEX	TX	MP NP	C4373	30	5	30	
			a	Olmesartan/Amlodipine - MYL 40/10	AF	MP NP	C4373	30	5	30	
			a	Olmesartan/Amlodipine Sandoz	SZ	MP NP	C4373	30	5	30	
			a	Pharmacor Olmesartan Amlodipine 40/10	CR	MP NP	C4373	30	5	30	
			a	Sevikar 40/10	AL	MP NP	C4373	30	5	30	

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

substitute:

	Wafer 8 mg	Oral		Zofran Zydis	AS	MP NP	C10498	10	1	10	

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

omit:

				DBL Oxaliplatin Concentrate	PF	MP		See Note 3	See Note 3	1	D(100)

[74] Schedule 1, Part 1, omit entry for Pancrelipase

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

insert in numerical order in the column headed "Circumstances": **C14727**

[76] Schedule 1, Part 1, entry for Pemetrexed in each of the forms: Powder for I.V. infusion 100 mg (as disodium); and Powder for I.V. infusion 500 mg (as disodium)

omit:

		Pemetrexed-AFT	AE	MP		See Note 3	See Note 3	1	D(100)

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

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

a	Pirfenidone Ameda	XT	MP	C13378 C13380 C13381	270	5	90	

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

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

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

a	Pirfenidone Ameda	XT	MP	C13380	90	5	90	

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

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

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

a	BTC Pregabalin	BG	MP NP	C4172	56	5	56	

[80] Schedule 1, Part 1, entry for Pyridostigmine

omit:

Tablet containing pyridostigmine bromide 180 mg (modified release) s19A	Oral	Pyridostigmine Bromide Extended-Release Tablets (Rising)	DZ	MP		100	5	30

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

omit:

	Tablet 25 mg (as potassium)	Oral	Isentress	MK	MP NP	C4274 C4275		360	5	60	D(100)
	Tablet 100 mg (as potassium)	Oral	Isentress	MK	MP NP	C4274 C4275		360	5	60	D(100)

[82] Schedule 1, Part 1, entry for Ranitidine

omit:

	Syrup 150 mg (as hydrochloride) per 10 mL, 300 mL	Oral	Zantac Syrup	AS	MP NP			2	5	1	

[83] Schedule 1, Part 1, entry for Riociguat

substitute:

Riociguat	Tablet 500 micrograms	Oral	Adempas	BN	MP	See Note 3	See Note 3	See Note 3	See Note 3	42	D(100)
	Tablet 1 mg	Oral	Adempas	BN	MP	See Note 3	See Note 3	See Note 3	See Note 3	42	D(100)
	Tablet 1.5 mg	Oral	Adempas	BN	MP	See Note 3	See Note 3	See Note 3	See Note 3	42	D(100)
	Tablet 2 mg	Oral	Adempas	BN	MP	See Note 3	See Note 3	See Note 3	See Note 3	42	D(100)
	Tablet 2.5 mg	Oral	Adempas	BN	MP	See Note 3	See Note 3	See Note 3	See Note 3	42	D(100)

[84] Schedule 1, Part 1, entry for Rosuvastatin in each of the forms: Tablet 5 mg (as calcium); Tablet 10 mg (as calcium); Tablet 20 mg (as calcium); and Tablet 40 mg (as calcium) *[Maximum Quantity: 60; Number of Repeats: 5]*

omit from the column headed "Authorised Prescriber" for the brand "Blooms Rosuvastatin": **MP NP NP** *substitute:* **MP NP**

[85] Schedule 1, Part 1, entry for Secukinumab

substitute:

Secukinumab	Injection 150 mg in 1 mL pre-filled pen	Injection	Cosentyx	NV	MP	C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155	P11390 P12392	1	0	1	

		C9429 C9431 C10431 C11089 C11096 C11138 C11154 C11389 C11390 C11502 C12392 C14220 C14430 C14462 C14655 C14662 C14670 C14692				
	MP	C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9429 C9431 C10431 C11089 C11096 C11138 C11154 C11389 C11390 C11502 C12392 C14220 C14430 C14462 C14655 C14662 C14670 C14692	P9064 P9429	1	2	1
	MP	C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9429 C9431 C10431 C11089 C11096 C11138 C11154 C11389 C11390 C11502 C12392 C14220 C14430 C14462 C14655 C14662 C14670 C14692	P9063 P9105 P9431 P10431 P14692	1	5	1
	MP	C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078	P8831 P9064	2	2	2

	C9105 C9155 C9429 C9431 C10431 C11089 C11096 C11138 C11154 C11389 C11390 C11502 C12392 C14220 C14430 C14462 C14655 C14662 C14670 C14692				
MP	C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9429 C9431 C10431 C11089 C11096 C11138 C11154 C11389 C11390 C11502 C12392 C14220 C14430 C14462 C14655 C14662 C14670 C14692	P6696 P8830 P8892 P9063 P9105	2	5	2
MP	C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9429 C9431 C10431 C11089 C11096 C11138 C11154 C11389 C11390 C11502 C12392 C14220 C14430 C14462 C14655 C14662 C14670 C14692	P9069 P9078 P9155 P14655 P14662 P14670	4	0	1
MP	C6696 C8830 C8831 C8892 C9063 C9064	P11389 P11502 P14220	5	0	1

						C9069 C9078 C9105 C9155 C9429 C9431 C10431 C11089 C11096 C11138 C11154 C11389 C11390 C11502 C12392 C14220 C14430 C14462 C14655 C14662 C14670 C14692				
					MP	C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9429 C9431 C10431 C11089 C11096 C11138 C11154 C11389 C11390 C11502 C12392 C14220 C14430 C14462 C14655 C14662 C14670 C14692	P9069 P9078 P9155 P11089 P11096 P11138 P11154 P14430 P14462	8	0	2

[86] Schedule 1, Part 1, entry for Sitagliptin with metformin in the form Tablet (modified release) containing 50 mg sitagliptin with 1000 mg metformin hydrochloride

substitute:

	Tablet (modified release) containing 50 mg sitagliptin with 1000 mg metformin hydrochloride	Oral	a	Janumet XR	XW	MP	C6333 C6334 C6344 C6443 C7507 C7530		56	5	56
						NP	C6333 C6334 C6344 C6443 C7530		56	5	56
			a	Sitagliptin/Metformin Sandoz XR	SZ	MP	C6333 C6334 C6344 C6443 C7507 C7530		56	5	56

						NP	C6333 C6334 C6344 C6443 C7530	56	5	56

[87] Schedule 1, Part 1, entry for Sitagliptin with metformin in the form Tablet (modified release) containing 100 mg sitagliptin with 1000 mg metformin hydrochloride

substitute:

	Tablet (modified release) containing 100 mg sitagliptin with 1000 mg metformin hydrochloride	Oral	a	Janumet XR	XW	MP	C6333 C6334 C6344 C6443 C7507 C7530	28	5	28
						NP	C6333 C6334 C6344 C6443 C7530	28	5	28
			a	Sitagliptin/Metformin Sandoz XR	SZ	MP	C6333 C6334 C6344 C6443 C7507 C7530	28	5	28
						NP	C6333 C6334 C6344 C6443 C7530	28	5	28

[88] Schedule 1, Part 1, omit entry for Sterculia with frangula bark

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

omit:

			a	DBL Tobramycin	PF	MP NP	C5446 C5490 C5519	10	1	5

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

(a) *omit from the column headed "Circumstances":* **P14195**

(b) *insert in numerical order in the column headed "Circumstances":* **C14195**

[91] Schedule 1, Part 1, entry for Tofacitinib

substitute:

Tofacitinib	Oral solution 1 mg per mL, 240 mL	Oral	Xeljanz	PF	MP	C9417 C14647 C14649 C14650 C14652 C14697	P9417 P14649 P14650 P14652	1	3	1
					MP	C9417 C14647 C14649 C14650 C14652 C14697	P14647 P14697	1	5	1
	Tablet 5 mg	Oral	Xeljanz	PF	MP	C9064 C9417 C9431 C11883 C11886 C11915 C11940 C11944 C11945 C11956 C11975 C11976 C11978 C12174 C12976 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14647 C14649 C14650 C14652 C14655 C14662 C14670 C14692 C14697 C14720	P9064 P9417 P11915 P11940 P11944 P11945 P11956 P11975 P11976 P12174 P14483 P14486 P14488 P14498 P14649 P14650 P14652 P14655 P14662 P14670	56	3	56
					MP	C9064 C9417 C9431 C11883 C11886 C11915 C11940 C11944 C11945 C11956 C11975 C11976 C11978 C12174 C12976 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14647 C14649 C14650 C14652 C14655 C14662 C14670 C14692	P9431 P11883 P11886 P11978 P12976 P14493 P14499 P14507 P14647 P14692 P14697 P14720	56	5	56

						C14697 C14720				
	Tablet 10 mg	Oral	Xeljanz	PF	MP	C11883 C11915 C11940 C11975 C11976 C12976	P11915 P11940 P11975 P11976	56	3	56
					MP	C11883 C11915 C11940 C11975 C11976 C12976	P11883 P12976	56	5	56

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

substitute:

Upadacitinib	Tablet 15 mg	Oral	Rinvoq	VE	MP	C9064 C9431 C10434 C11886 C11944 C11945 C11956 C11978 C12174 C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011 C14198 C14199 C14208 C14213 C14216 C14217 C14483 C14486 C14488 C14498 C14613 C14633 C14655 C14662 C14670 C14692 C14696 C14698 C14709	P13959	28	1	28
					MP	C9064 C9431 C10434 C11886 C11944 C11945 C11956 C11978 C12174 C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011 C14198 C14199	P9064 P11944 P11945 P11956 P12174 P12504 P14208 P14213 P14216 P14217 P14483 P14486 P14488 P14498 P14655 P14662 P14670	28	3	28

		C14208 C14213 C14216 C14217 C14483 C14486 C14488 C14498 C14613 C14633 C14655 C14662 C14670 C14692 C14696 C14698 C14709				
	MP	C9064 C9431 C10434 C11886 C11944 C11945 C11956 C11978 C12174 C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011 C14198 C14199 C14208 C14213 C14216 C14217 C14483 C14486 C14488 C14498 C14613 C14633 C14655 C14662 C14670 C14692 C14696 C14698 C14709	P12499 P12508	28	4	28
	MP	C9064 C9431 C10434 C11886 C11944 C11945 C11956 C11978 C12174 C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011 C14198 C14199 C14208 C14213 C14216 C14217 C14483 C14486 C14488 C14498	P9431 P10434 P11886 P11978 P12493 P12494 P13930 P13958 P14011 P14198 P14199 P14613 P14633 P14692 P14696 P14698 P14709	28	5	28

					C14613 C14633 C14655 C14662 C14670 C14692 C14696 C14698 C14709				
Tablet 30 mg	Oral	Rinvoq	VE	MP	C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011 C14696 C14698 C14711 C14728	P13959	28	1	28
				MP	C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011 C14696 C14698 C14711 C14728	P14711	28	2	28
				MP	C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011 C14696 C14698 C14711 C14728	P12504	28	3	28
				MP	C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011 C14696 C14698 C14711 C14728	P12499 P12508	28	4	28
				MP	C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011 C14696 C14698 C14711	P12493 P12494 P13930 P13958 P14011 P14696 P14698 P14728	28	5	28

						C14728				
	Tablet 45 mg	Oral	Rinvoq	VE	MP	C11976 C13990 C13999 C14014 C14653 C14696 C14710 C14721 C14734	P14653 P14696 P14710 P14721 P14734	28	2	28
					MP	C11976 C13990 C13999 C14014 C14653 C14696 C14710 C14721 C14734	P11976 P13990 P13999 P14014	28	3	28

[93] Schedule 1, Part 1, entry for Vancomycin in the form Powder for injection 500 mg (500,000 I.U.) (as hydrochloride)

substitute:

	Powder for injection 500 mg (500,000 I.U.) (as hydrochloride)	Injection	Vancomycin Alphapharm	AF	MP	C5716 C5717 C5769	P5717	2	0	1
					PDP	C5801		2	0	1
					MP	C5716 C5717 C5769	P5716 P5769	5	0	1

[94] Schedule 1, Part 1, entry for Vancomycin in the form Powder for injection 1 g (1,000,000 I.U.) (as hydrochloride)

substitute:

	Powder for injection 1 g (1,000,000 I.U.) (as hydrochloride)	Injection	Vancomycin Alphapharm	AF	MP	C5716 C5717 C5769	P5717	1	0	1
					PDP	C5801		1	0	1
					MP	C5716 C5717 C5769	P5716 P5769	3	0	1

[95] Schedule 1, Part 1, entry for Voriconazole in the form Tablet 50 mg

(a) *omit:*

		a	Vfend	PF	MP NP	C4683 C4685	P4685	56	0	56

						C5692 C5725 C5748					

(b) *omit:*

			a	Vfend	PF	MP NP	C4683 C4685 C5692 C5725 C5748	P4683 P5692 P5725 P5748	56	2	56

[96] Schedule 1, Part 1, entry for Zoledronic acid in the form Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL

substitute:

Zoledronic acid	Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL	Injection		Zoledronic Acid Accord	OC	MP	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328 C14729 C14735	P14729 P14735	1	0	1	PB(100)
			a	APO-Zoledronic Acid	TX	MP	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11	1	PB(100)
			a	DEZTRON	DZ	MP	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11	1	PB(100)
			a	Zoledronate-DRLA 4	RZ	MP	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11	1	PB(100)
			a	Zoledronic Acid Accord	OC	MP	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328 C14729 C14735	P5605 P5703 P5704 P5735 P9268 P9304 P9317 P9328	1	11	1	PB(100)
			a	Zometa	SA	MP	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11	1	PB(100)

[97] Schedule 1, Part 2, after entry for Ertugliflozin with sitagliptin in the form Tablet containing 15 mg ertugliflozin with 100 mg sitagliptin

insert:

Essential amino acids formula with vitamins and minerals	Sachets containing oral powder 12.5 g, 50 (EAA Supplement)	Oral	EAA Supplement	VF	MP NP	C4925 C4958		4	5	1	
Estradiol with dydrogesterone	Tablet 1 mg-5 mg	Oral	Femoston-Conti	GO	MP NP			28	5	28	
Filgrastim	Injection 300 micrograms in 1 mL	Injection	Neupogen	AN	MP	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11	10	D(100)
	Injection 480 micrograms in 1.6 mL	Injection	Neupogen	AN	MP	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11	10	D(100)
Insulin neutral with insulin isophane	Injections (human), cartridges, 50 units-50 units per mL, 3 mL, 5	Injection	Mixtard 50/50 Penfill 3 mL	NO	MP NP			5	1	1	

[98] Schedule 1, Part 2, omit entry for Labetalol

[99] Schedule 1, Part 2, after entry for Insulin neutral with insulin isophane

insert:

Macrogol 3350	Oral liquid 13.125 g in 25 mL with electrolytes, 500 mL	Oral	Movicol Liquid	NE	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P6171	2	3	1	

					MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P4576 P4577 P4580 P4596 P4601	2	5	1		
Pancrelipase	Capsule (containing enteric coated microtablets) providing not less than 25,000 BP units of lipase activity	Oral	Panzytrat 25000	TM	MP NP			200	10	100		
					MP		P5779	200	21	100		
Raltegravir	Tablet 25 mg (as potassium)	Oral	Isentress	MK	MP NP	C4274 C4275		360	5	60	D(100)	
	Tablet 100 mg (as potassium)	Oral	Isentress	MK	MP NP	C4274 C4275		360	5	60	D(100)	
Sterculia with frangula bark	Granules 620 mg-80 mg per g, 500 g	Oral	Normacol Plus	NE	MP NP	C5613 C5640 C5685 C5720 C5775 C5776 C5804 C6139	P5613 P5640 P5685 P5720 P5775 P5776 P5804	1	1	1		
					MP NP	C5613 C5640 C5685 C5720 C5775 C5776 C5804 C6139	P6139	1	3	1		

[100] Schedule 3, after details relevant to Responsible Person code IT

insert:

IU	AU Pharma Pty Ltd	84 132 146 313

[101] Schedule 4, Part 1, entry for Adalimumab

(a) *omit:*

	C11634	P11634		Ankylosing spondylitis 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 an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	Compliance with Authority Required procedures - Streamlined Authority Code 11634

				An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. 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.	

(b) *omit:*

	C12131	P12131		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or	Compliance with Written Authority Required procedures

				(c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 4 weeks old at the time of application. 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.	

(c) *omit:*

	C12175	P12175		Ankylosing spondylitis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	Compliance with Authority Required procedures
	C12176	P12176		Ankylosing spondylitis 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 an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided 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 following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	

(d) *omit:*

	C12234	P12234		Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 4 weeks old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	Compliance with Written Authority Required procedures

				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.	

(e) *omit:*

	C13606	P13606		Ankylosing spondylitis 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 a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a BASDAI score. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	Compliance with Written Authority Required procedures

(f) *omit:*

	C13682	P13682		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.	Compliance with Written Authority Required procedures

				Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	

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

	C14655	P14655		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity	Compliance with Written Authority Required procedures

				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.	
	C14656	P14656		Ankylosing spondylitis Subsequent continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	Compliance with Written Authority Required procedures
	C14662	P14662		Ankylosing spondylitis 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 a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological	Compliance with Written Authority Required procedures

				medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14670	P14670		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND	Compliance with Written Authority Required procedures

				Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-	

				subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14672	P14672		Ankylosing spondylitis 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 a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	Compliance with Authority Required procedures
	C14673	P14673		Ankylosing spondylitis	Compliance with

				Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	Authority Required procedures
	C14683	P14683		Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR	Compliance with Authority Required procedures - Streamlined Authority Code 14683

				Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. 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.	
	C14701	P14701		Ankylosing spondylitis Subsequent continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 14701

	C14713	P14713		Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	Compliance with Written Authority Required procedures
	C14730	P14730		Ankylosing spondylitis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	Compliance with Authority Required procedures

[102] Schedule 4, Part 1, entry for Atorvastatin

omit:

		P7598		For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	

[103] Schedule 4, Part 1, entry for Bimekizumab

(a) *omit:*

	C14438	P14438		Severe chronic plaque psoriasis Grandfathered patient - Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) Patient must have a documented severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where lesions have been present for at least 6 months prior to commencing non-PBS-subsidised treatment with this drug for this condition; AND Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 October 2023; AND Patient must have a documented failure to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments prior to commencing non-PBS-subsidised treatment with this drug for this condition: (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 weekly for at least 6 weeks; (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND Patient must have a documented Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing non-PBS-subsidised treatment with this drug for this condition; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. 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 authority application must be made in writing and must include: (a) a completed authority prescription form; 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 sheets including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and (c) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. The most recent PASI assessment must be no more than 4 weeks old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response conducted following a	Compliance with Written Authority Required procedures

				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.	

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

	C14726	P14726		Severe chronic plaque psoriasis Grandfathered patient - Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) Patient must have a documented severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where lesions have been present for at least 6 months prior to commencing non-PBS-subsidised treatment with this drug for this condition; AND Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 October 2023; AND Patient must have a documented failure to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments prior to commencing non-PBS-subsidised treatment with this drug for this condition: (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 weekly for at least 6 weeks; (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND Patient must have had disease, prior to treatment with this drug for this condition, 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 were rated as severe or very severe; or (ii) the skin area affected was 30% or more of the face, palm of a hand or sole of a foot; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. 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 authority application must be made in writing and must include: (a) a completed authority prescription form; 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 sheets including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and (c) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. The most recent PASI assessment must be no more than 4 weeks old at the time of application. 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.	Compliance with Written Authority Required procedures

[104] Schedule 4, Part 1, entry for Certolizumab pegol

(a) *omit:*

	C9430	P9430		Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	Compliance with Written Authority Required procedures

(b) *omit:*

	C9442	P9442		Ankylosing spondylitis 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 a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis;	Compliance with Written Authority Required procedures

				AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C9537	P9537		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and	Compliance with Written Authority Required procedures

				(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. 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. 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.	
	C9610	P9610		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.	Compliance with Written Authority Required procedures

				If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application. Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	

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

	C14659	P14659		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.	Compliance with Written Authority Required procedures

				Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14686	P14686		Ankylosing spondylitis 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 a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND	Compliance with Written Authority Required procedures

				The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14692	P14692		Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND	Compliance with Written Authority Required procedures

				Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14714	P14714		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/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 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a	Compliance with Written Authority Required procedures

				response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	

[105] Schedule 4, Part 1, entry for Darolutamide

insert in numerical order after existing text:

	C14034			Metastatic castration sensitive carcinoma of the prostate The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy; AND Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug. Patient must be undergoing concurrent androgen deprivation therapy.	Compliance with Authority Required procedures

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

(a) *insert after entry for Circumstances Code "C10126":*

	C10206			Extensive-stage small cell lung cancer Initial treatment	Compliance with Authority Required

				The condition must be previously untreated; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be in combination with etoposide and a platinum-based antineoplastic drug.	procedures - Streamlined Authority Code 10206
	C10509			Extensive-stage small cell lung cancer Continuing treatment - 4 weekly treatment regimen The treatment must be as monotherapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 10509

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

	C14708			Locally advanced, metastatic or recurrent biliary tract cancer (intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer) Patient must have either of the following at treatment initiation: (i) locally advanced biliary tract cancer that is untreated with systemic anti-cancer therapy in the unresectable setting, (ii) metastatic biliary tract cancer that is untreated with systemic anti-cancer therapy in the metastatic setting. Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. The treatment must be/have been initiated with both: (i) gemcitabine, (ii) cisplatin (refer to Product Information of gemcitabine and cisplatin for dosing information); AND Patient must not have developed disease progression while being treated with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 14708

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

(a) *omit:*

	C9410	P9410		Ankylosing spondylitis Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a	Compliance with Written Authority Required procedures

				minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. 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. 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.	
	C9429	P9429		Ankylosing spondylitis Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	Compliance with Authority Required procedures

(b) *omit:*

	C9481	P9481		Ankylosing spondylitis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. 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	Compliance with Authority Required procedures - Streamlined Authority Code 9481

				Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be used to determine response for all subsequent continuing treatments. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. 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. 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.	
	C9487	P9487		Ankylosing spondylitis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	Compliance with Authority Required procedures
	C9502	P9502		Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.	Compliance with Written Authority Required procedures

				All measurements provided must be no more than 1 month old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. 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.	
	C9554	P9554		Ankylosing spondylitis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. 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 not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	Compliance with Written Authority Required procedures

(c) *omit:*

	C13535	P13535		Ankylosing spondylitis	Compliance with Written

				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 a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	Authority Required procedures

(d) *omit:*

	C13540	P13540		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND	Compliance with Written Authority Required procedures

				Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application. Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	

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

	C14655	P14655		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	Compliance with Written Authority Required procedures
	C14656	P14656		Ankylosing spondylitis	Compliance with Written

				Subsequent continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	Authority Required procedures
	C14662	P14662		Ankylosing spondylitis 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 a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology	Compliance with Written Authority Required procedures

				Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14670	P14670		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory	Compliance with Written Authority Required procedures

				drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14671	P14671		Ankylosing spondylitis 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	Compliance with Authority Required procedures

				Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14673	P14673		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction.	Compliance with Authority Required procedures

				Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14683	P14683		Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline.	Compliance with Authority Required procedures - Streamlined Authority Code 14683

				Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. 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.	
	C14701	P14701		Ankylosing spondylitis Subsequent continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 14701
	C14703	P14703		Ankylosing spondylitis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply 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. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	
	C14713	P14713		Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	Compliance with Written Authority Required procedures
	C14715	P14715		Ankylosing spondylitis Continuing treatment - balance of supply	Compliance with Authority Required

				Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	procedures

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

omit:

		P7640		For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	

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

omit:

		P7598		For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	

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

omit:

		P7640		For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	

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

(a) *omit:*

	C9414	P9414		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include:	Compliance with Written Authority Required procedures

				(a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. 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. 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.	
	C9428	P9428		Ankylosing spondylitis 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 a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR	Compliance with Written Authority Required procedures

				Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	

(b) *omit:*

	C9430	P9430		Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date	Compliance with Written Authority Required procedures

				of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. 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.	

(c) *omit:*

	C9503	P9503		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application. Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the	Compliance with Written Authority Required procedures

				reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	

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

	C14655	P14655		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI	Compliance with Written Authority Required procedures

				score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14662	P14662		Ankylosing spondylitis 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 a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records:	Compliance with Written Authority Required procedures

				(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14670	P14670		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and	Compliance with Written Authority Required procedures

				exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14692	P14692		Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records.	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 these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	

[112] Schedule 4, Part 1, entry for Ibandronic acid

omit:

	C5291			Bone metastases The condition must be due to breast cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 5291
	C9333			Bone metastases The condition must be due to breast cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 9333

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

(a) *omit:*

	C13095	P13095		Ankylosing spondylitis Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND The treatment must have both: (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and	Compliance with Written Authority Required procedures

				(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application.	

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

	C14668	P14668		Ankylosing spondylitis Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND The treatment must have both: (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. All measurements provided must be no more than 1 month old at the time of application.	Compliance with Written Authority Required procedures
	C14683	P14683		Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	Compliance with Authority Required procedures - Streamlined Authority Code 14683

				An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. 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.	
	C14689	P14689		Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 14689
	C14701	P14701		Ankylosing spondylitis Subsequent continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this	Compliance with Authority Required procedures -

				condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. 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.	Streamlined Authority Code 14701
	C14723	P14723		Ankylosing spondylitis Subsequent continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.	Compliance with Authority Required procedures - Streamlined Authority Code 14723

				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.	

[114] Schedule 4, Part 1, entry for Ixekizumab

(a) *omit:*

	C10997	P10997		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 4 weeks old at the time of application. 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.	Compliance with Written Authority Required procedures

				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.	
	C11030	P11030		Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 4 weeks old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	Compliance with Written Authority Required procedures
	C11054	P11054		Ankylosing spondylitis 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 a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise	Compliance with Written Authority Required procedures

				but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a BASDAI score. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C11061	P11061		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR	Compliance with Written Authority Required procedures

				Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	

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

	C14655	P14655		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction.	Compliance with Written Authority Required procedures

				Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14662	P14662		Ankylosing spondylitis 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 a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology	Compliance with Written Authority Required procedures

				Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14670	P14670		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory	Compliance with Written Authority Required procedures

				drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14692	P14692		Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this	Compliance with Written Authority Required procedures

				condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	

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

(a) *omit:*

	C13888			Advanced or metastatic gastro-oesophageal cancers The condition must be a gastro-oesophageal cancer type as specified in the drug's 'Indications' section of the approved Australian Product Information; AND The treatment must be prescribed in accordance with the drug's 'Indications' section of the approved Australian Production Information with respect to each of: (i) concomitant drugs/therapies, (ii) line of therapy (i.e. prior treatments, if any); AND Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND Patient must be untreated with programmed cell death-1/ligand-1 (PD-1/PD-L1) inhibitor therapy for gastro-oesophageal cancer. Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the	Compliance with Authority Required procedures - Streamlined Authority Code 13888

				following, whichever comes first: (i) disease progression despite treatment with this drug, (ii) 24 months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.	

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

	C14676			Advanced or metastatic gastro-oesophageal cancers Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND Patient must be untreated (up until initiating this drug) with programmed cell death-1/ligand-1 (PD-1/PD-L1) inhibitor therapy for gastro-oesophageal cancer. Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first: (i) disease progression despite treatment with this drug, (ii) 24 months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs. Patient must be in one of the three population subsets described below. Population 1 Conditions: gastric cancer, gastro-oesophageal junction cancer, oesophageal adenocarcinoma Concomitant therapies: chemotherapy containing at least a fluoropyrimidine drug plus a platinum drug Line of treatment: first-line drug treatment Additional clinical finding: HER2 negative Population 2 Condition: oesophageal squamous cell carcinoma (can be recurrent) Concomitant therapies: chemotherapy containing at least a fluoropyrimidine drug plus a platinum drug Line of treatment: first-line drug treatment Additional clinical finding: unresectable Population 3 Condition: oesophageal squamous cell carcinoma (can be recurrent) Line of treatment: second-line drug treatment after chemotherapy containing at least a fluoropyrimidine drug plus a platinum drug Additional clinical finding: unresectable	Compliance with Authority Required procedures - Streamlined Authority Code 14676

[116] Schedule 4, Part 1, entry for Pancreatic extract

omit:

		P5779		Cystic fibrosis Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	

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

insert in numerical order after existing text:

	C14727			Stage II or Stage III triple negative breast cancer The treatment must be initiated in combination with neoadjuvant chemotherapy; AND	Compliance with Authority Required

				The condition must not have progressed/recurred whilst on treatment with this drug. Patient must not be undergoing treatment with this drug beyond 52 cumulative weeks under this restriction; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 7 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 4 repeat prescriptions.	procedures - Streamlined Authority Code 14727

[118] Schedule 4, Part 1, entry for Pravastatin

omit:

		P7598		For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	

[119] Schedule 4, Part 1, entry for Rosuvastatin

omit:

		P7598		For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	

[120] Schedule 4, Part 1, entry for Secukinumab

(a) *omit:*

	C9414	P9414		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of	Compliance with Written Authority Required procedures

				completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. 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. 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.	
	C9428	P9428		Ankylosing spondylitis 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 a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and	Compliance with Written Authority Required procedures

				(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	

(b) *omit:*

	C9430	P9430		Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. 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-	Compliance with Written Authority Required procedures

				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.	

(c) *omit:*

	C9503	P9503		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application. Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks	Compliance with Written Authority Required procedures

				of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	

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

	C14655	P14655		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to	Compliance with Written Authority Required procedures

				respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14662	P14662		Ankylosing spondylitis 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 a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the	Compliance with Written Authority Required procedures

				date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14670	P14670		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Written Authority Required procedures

				The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14692	P14692		Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	Compliance with Written Authority Required procedures

				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.	

[121] Schedule 4, Part 1, entry for Simvastatin

omit:

		P7598		For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	

[122] Schedule 4, Part 1, entry for Sulfasalazine

omit:

		P4894		For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	

[123] Schedule 4, Part 1, entry for Tofacitinib

(a) *insert after entry for Circumstances Code "C9064":*

	C9417	P9417		Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) 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 12 months) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	Compliance with Authority Required procedures

(b) *omit:*

	C9429	P9429		Ankylosing spondylitis Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to	Compliance with Authority Required procedures

				complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	

(c) *insert after entry for Circumstances Code "C11978":*

	C12174	P12174		Ankylosing spondylitis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	Compliance with Authority Required procedures

(d) *omit:*

	C14210	P14210		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent	Compliance with Written Authority Required procedures

				course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 4 weeks old at the time of application. 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.	
	C14211	P14211		Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 4 weeks old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will	Compliance with Written Authority Required procedures

				enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14224	P14224		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and	Compliance with Written Authority Required procedures

				(b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14225	P14225		Ankylosing spondylitis 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 a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a BASDAI score. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks	Compliance with Written Authority Required procedures

				of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14345	P14345		Ankylosing spondylitis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2023; AND Patient must have had at least 2 of the following prior to commencing non-PBS-subsidised treatment: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months prior to commencing non-PBS-subsidised treatment; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response to NSAIDs and must have been demonstrated prior to initiation of non-PBS subsidised treatment with this biological medicine for this condition: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must have been determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. If the above requirement to demonstrate an elevated ESR or CRP could not be met, the application must state the reason this criterion could not be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and	Compliance with Written Authority Required procedures

				(b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	

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

	C14647	P14647		Severe active juvenile idiopathic arthritis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 December 2023; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate prior to initiating treatment with this drug for this condition; OR Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens prior to initiating treatment with this drug for this condition: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be under 18 years of age. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses	Compliance with Authority Required procedures

				over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: (a) an active joint count of at least 20 active (swollen and tender) joints; OR (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to prior treatment must be documented in the patient's medical records. The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records: (a) the date of assessment of severe active juvenile idiopathic arthritis; and (b) details of prior treatment including dose and duration of treatment. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. 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.	
	C14649	P14649		Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. 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 receive more than 16 weeks of treatment under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or	Compliance with Authority Required procedures

				(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. 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 12 months 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 a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C14650	P14650		Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. 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 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Active joints are defined as: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records: (a) the date of assessment of severe active juvenile idiopathic arthritis; and	Compliance with Authority Required procedures

				(b) the date of the last continuing prescription. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. 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.	
	C14652	P14652		Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: (a) an active joint count of at least 20 active (swollen and tender) joints; OR (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).	Compliance with Authority Required procedures

				The assessment of response to prior treatment must be documented in the patient's medical records. The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records: (a) the date of assessment of severe active juvenile idiopathic arthritis; and (b) details of prior treatment including dose and duration of treatment. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. 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.	
	C14655	P14655		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same	Compliance with Written Authority Required procedures

				marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14662	P14662		Ankylosing spondylitis 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 a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level.	Compliance with Written Authority Required procedures

				To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14670	P14670		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include:	Compliance with Written Authority Required procedures

				(1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14692	P14692		Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.	Compliance with Written Authority Required procedures

				If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A 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.	
	C14697	P14697		Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. 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 12 months 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 a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	Compliance with Authority Required procedures - Streamlined Authority Code 14697
	C14720	P14720		Ankylosing spondylitis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2023; AND	Compliance with Written Authority Required procedures

				Patient must have had at least 2 of the following prior to commencing non-PBS-subsidised treatment: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months prior to commencing non-PBS-subsidised treatment; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response to NSAIDs and must have been demonstrated prior to initiation of non-PBS subsidised treatment with this biological medicine for this condition: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must have been determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. If the above requirement to demonstrate an elevated ESR or CRP could not be met, the application must state the reason this criterion could not be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline.	

				Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	

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

(a) *insert in the column headed "Purposes Code" for the Circumstances Code "C11976":* **P11976**

(b) *omit:*

	C12090	P12090		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:	Compliance with Written Authority Required procedures

				(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C12091	P12091		Ankylosing spondylitis 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 a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction.	Compliance with Written Authority Required procedures

				Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a BASDAI score. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C12142	P12142		Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 4 weeks old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to	Compliance with Written Authority Required procedures

				respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	

(c) *insert after entry for Circumstances Code "C11978":*

	C12174	P12174		Ankylosing spondylitis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	Compliance with Authority Required procedures

(d) *omit:*

	C12184	P12184		Ankylosing spondylitis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	Compliance with Authority Required procedures
	C12246	P12246		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)	Compliance with Written Authority Required

				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 receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 4 weeks old at the time of application. 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.	procedures

(e) *insert in the column headed "Purposes Code" for the Circumstances Code "C13990":* **P13990**

(f) *insert in the column headed "Purposes Code" for the Circumstances Code "C13999":* **P13999**

(g) *insert in the column headed "Purposes Code" for the Circumstances Code "C14014":* **P14014**

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

	C14653	P14653		Severe Crohn disease Balance of supply for Initial (induction) treatment phases Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. The treatment must have been prescribed in a quantity in the most recent prescription which did not seek the full quantity available in regards to any of: (i) the quantity per dispensing, (ii) repeat prescriptions; AND The treatment must provide no more than the balance available under the treatment phase from which the immediately preceding supply was obtained under.	Compliance with Authority Required procedures
	C14655	P14655		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.	Compliance with Written Authority Required procedures

				If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A 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.	
	C14662	P14662		Ankylosing spondylitis 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 a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the	Compliance with Written Authority Required procedures

				continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14670	P14670		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records:	Compliance with Written Authority Required procedures

				(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14692	P14692		Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-	Compliance with Written Authority Required procedures

				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.	
	C14696	P14696		Severe Crohn disease 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 December 2023; AND Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following: (a) patient must have evidence of intestinal inflammation; (b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient. 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. All assessments, pathology tests and diagnostic imaging studies were to have been within 4 weeks leading up to commencing the non-PBS subsidised supply of this drug and should have been performed preferably whilst still on	Compliance with Written Authority Required procedures

				conventional treatment, but no longer than 4 weeks following the last dose of conventional treatment. Where extensive small intestinal disease affecting more than 50 cm of the small intestine applies, the CDAI must have been at least 220 prior to commencing the non-PBS subsidised supply of this drug. 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, details 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. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.	
	C14698	P14698		Severe Crohn disease Balance of supply for the Continuing (maintenance) treatment phase Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. The treatment must have been prescribed in a quantity in the most recent prescription which did not seek the full quantity available in regards to any of: (i) the quantity per dispensing, (ii) repeat prescriptions; AND The treatment must provide no more than the balance available under the treatment phase from which the immediately preceding supply was obtained under.	Compliance with Authority Required procedures
	C14709	P14709		Severe Crohn disease Continuing (maintenance) treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). In relation to the immediately preceding supply of this biological medicine, provide at least one of the following which is not	Compliance with Written Authority Required procedures

				more than 4 weeks from the last administered dose: (i) the Crohn Disease Activity Index (CDAI) score, including the date the score was calculated on; or (ii) the unique serial/identifying number and date(s) of pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant.	
	C14710	P14710		Severe Crohn disease Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have 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 severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND Patient must have evidence of intestinal inflammation; OR Patient must be assessed clinically as being in a high faecal output state; OR Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Provide at least one of the following: (i) the current Crohn Disease Activity Index (CDAI) score, including the date this score was calculated on; (ii) confirmation that there is a documented history of intestinal inflammation plus diagnostic imaging/surgical evidence of at least one of: (a) short gut syndrome, (b) ileostomy, (c) colostomy; (iii) confirmation that there is a documented history and radiological evidence of intestinal inflammation from extensive small intestinal disease affecting more than 50 cm of the small intestine where the CDAI score is at least 220, but below 300. 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. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for	Compliance with Written Authority Required procedures

				continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.	
	C14711	P14711		Severe Crohn disease Extended induction period (optional) from weeks 12 to 24 Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have experienced an inadequate therapeutic benefit following at least one of: (i) dosing with 45 mg daily in the initial 12-week induction period, (ii) dosing with 15 mg daily. Patient must be at least 18 years of age.	Compliance with Authority Required procedures
	C14721	P14721		Severe Crohn disease Initial 1 (induction treatment covering the first 12 weeks in a patient untreated with biological medicine) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must be at least 18 years of age. Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following: (a) patient must have evidence of intestinal inflammation; (b) patient must be assessed clinically as being in a high faecal output state;	Compliance with Written Authority Required procedures

				(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient. 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. All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. 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, details 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. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.	
	C14728	P14728		Severe Crohn disease Continuing (maintenance) treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; OR The condition must have not met the improvements specified above due to the prescribed dose being too low - this authority application seeks higher dosing. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). In relation to the immediately preceding supply of this biological medicine, provide at least one of the following which is not	Compliance with Written Authority Required procedures

				more than 4 weeks from the last administered dose: (i) the Crohn Disease Activity Index (CDAI) score, including the date the score was calculated on; or (ii) the unique serial/identifying number and date(s) of pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant.	
	C14734	P14734		Severe Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND The treatment must not have on a previous occasion failed to provide the patient with an adequate response during the current treatment cycle. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). In relation to the biological medicine prescribed immediately before this one, provide at least one of the following which is not more than 4 weeks from the last administered dose: (i) the Crohn Disease Activity Index (CDAI) score, including the date the score was calculated on; or (ii) the unique serial/identifying number and date(s) of pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; or (iii) confirmation that a severe intolerance occurred that resulted in the cessation of treatment.	Compliance with Written Authority Required procedures

[125] Schedule 4, Part 1, entry for Zoledronic acid

(a) *insert in the column headed "Purposes Code" for the Circumstances Code "C5605":* **P5605**

(b) *insert in the column headed "Purposes Code" for the Circumstances Code "C5703":* **P5703**

(c) *insert in the column headed "Purposes Code" for the Circumstances Code "C5704":* **P5704**

(d) *insert in the column headed "Purposes Code" for the Circumstances Code "C5735":* **P5735**

(e) *insert in the column headed "Purposes Code" for the Circumstances Code "C9268":* **P9268**

(f) *insert in the column headed "Purposes Code" for the Circumstances Code "C9304":* **P9304**

(g) *insert in the column headed "Purposes Code" for the Circumstances Code "C9317":* **P9317**

(h) *insert in the column headed "Purposes Code" for the Circumstances Code "C9328":* **P9328**

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

	C14729	P14729		Adjuvant management of breast cancer Patient must be post-menopausal. Patient must not be undergoing PBS-subsidised treatment with this drug for this indication for more than 36 months.	Compliance with Authority Required procedures - Streamlined Authority Code 14729
	C14735	P14735		Adjuvant management of breast cancer Patient must be post-menopausal. Patient must not be undergoing PBS-subsidised treatment with this drug for this indication for more than 36 months.	Compliance with Authority Required procedures - Streamlined Authority Code 14735

[126] Schedule 5, after entry for Adalimumab

insert:

Adefovir	GRP-28116	Tablet containing adefovir dipivoxil 10 mg	Oral	APO-Adefovir
		Tablet containing adefovir dipivoxil 10 mg (S19A)	Oral	Adefovir Dipivoxil Tablets 10 mg (SigmaPharm Laboratories)

[127] Schedule 5, omit entry for Amoxicillin

[128] Schedule 5, entry for Amoxicillin with clavulanic acid in the form Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *[GRP-26768]*

insert in alphabetical order in the column headed "Brand": **Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125**

[129] Schedule 5, entry for Clopidogrel in the form Tablet 75 mg (as hydrogen sulfate)

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

[130] Schedule 5, entry for Filgrastim in the form Injection 300 micrograms in 0.5 mL single-use pre-filled syringe *[GRP-23379]*

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

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

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

[132] Schedule 5, entry for Imatinib in the form Capsule 100 mg (as mesilate) *[GRP-21074]*

omit from the column headed "Brand": **CIPLA IMATINIB ADULT**

[133] Schedule 5, entry for Imatinib

omit:

	GRP-25645	Capsule 100 mg (as mesilate)	Oral	IMATINIB-DRLA Imatinib-APOTEX
		Tablet 100 mg (as mesilate)	Oral	Gilmat Glivec IMATINIB RBX Imatinib-Teva

[134] Schedule 5, entry for Imatinib in the form Capsule 400 mg (as mesilate) *[GRP-21079]*

omit from the column headed "Brand": **CIPLA IMATINIB ADULT**

[135] Schedule 5, entry for Imatinib

omit:

	GRP-25647	Capsule 400 mg (as mesilate)	Oral	Imatinib-APOTEX IMATINIB-DRLA Imatinib GH
		Tablet 400 mg (as mesilate)	Oral	Gilmat Glivec IMATINIB RBX Imatinib-Teva

[136] Schedule 5, entry for Meloxicam in the form Tablet 7.5 mg *[GRP-15658]*

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

[137] Schedule 5, after entry for Morphine in the form Injection containing morphine sulfate pentahydrate 10 mg in 1 mL

insert:

	GRP-28109	Oral solution containing morphine hydrochloride trihydrate 2 mg per mL, 1 mL	Oral	Ordine 2
		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)
		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)

		Oral solution containing morphine sulfate 10 mg per 5 mL in 100 mL bottle, 1 mL (S19A)	Oral	Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL
		Oral solution containing morphine sulfate 10 mg per 5 mL in 300 mL bottle, 1 mL (S19A)	Oral	Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL

[138] Schedule 5, entry for Olanzapine in the form Tablet 20 mg (orally disintegrating) *[GRP-15643]*

insert in alphabetical order in the column headed "Brand": **Zypine ODT**

[139] Schedule 5, entry for Olanzapine in the form Wafer 20 mg *[GRP-15643]*

omit from the column headed "Brand": **Zypine ODT**

[140] Schedule 5, entry for Olanzapine in the form Tablet 10 mg (orally disintegrating) *[GRP-15723]*

insert in alphabetical order in the column headed "Brand": **Zypine ODT**

[141] Schedule 5, entry for Olanzapine in the form Wafer 10 mg *[GRP-15723]*

omit from the column headed "Brand": **Zypine ODT**

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

insert in alphabetical order in the column headed "Brand": **Zypine ODT**

[143] Schedule 5, entry for Olanzapine in the form Wafer 5 mg *[GRP-15797]*

omit from the column headed "Brand": **Zypine ODT**

[144] Schedule 5, entry for Olanzapine in the form Tablet 15 mg (orally disintegrating) *[GRP-15953]*

insert in alphabetical order in the column headed "Brand": **Zypine ODT**

[145] Schedule 5, entry for Olanzapine in the form Wafer 15 mg *[GRP-15953]*

omit from the column headed "Brand": **Zypine ODT**

[146] Schedule 5, entry for Ondansetron

omit:

	GRP-17042	Tablet (orally disintegrating) 8 mg	Oral	APO-Ondansetron ODT APX-Ondansetron ODT Ondansetron AN ODT Ondansetron Mylan ODT Ondansetron ODT-DRLA

				Ondansetron SZ ODT Zotren ODT
		Wafer 8 mg	Oral	Zofran Zydis

[147] Schedule 5, omit entry for Pancrelipase

[148] Schedule 5, omit entry for Pyridostigmine