

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

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	2	Commencement	
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Na	ational H	ealth (Listing of Pharmaceutical Benefits) Instrument 2012	
(P	B 71 of 2	012).	2

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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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	See Note	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	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	P11716 P11761 P11852 P11854	2	3	1	
				MP	C9715 C11579 C11713 C11715 C11716 C11717 C11718 C11761 C11767 C11852 C11853 C11854 C11855 C11903 C11966	P11853 P11903	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 C11906 C12098 C12101	P11713	2	0	2	

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		C12147 C12148				
		C12155 C12156				
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		C12190 C12194				
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		C13609 C13612				
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		C14493 C14498				
		C14499 C14507				
		C14499 C14507				
		C14655 C14656 C14662 C14670				
		C14002 C14070				
		C14713 C14730	,			
Yuflyma	EW MP	C9064 C9386	P11713	2	0	2
Tullyllia	∟vv ivii	C9715 C11107	1 11/13	2	U	2
		C11523 C11524				
		C11529 C11579				
		C11604 C11606				
		C11631 C11635				
		C11704 C11709				
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		C14656 C14662		
		C14670 C14672		
		C14673 C14683		
		C14701 C14713		
		C14730		
Humira	VE MP	C9064 C9386 P9715 P11709 2	2	2
Humira	VE MP	C9064 C9386 P9715 P11709 2	2	2
Humira	VE MP		2	2
Humira	VE MP	C9064 C9386 P9715 P11709 2 C9715 C11107 P11715 P11716 C11704 C11709 P11759 P11761	2	2
Humira	VE MP	C9064 C9386 P9715 P11709 2 C9715 C11107 P11715 P11716	2	2
Humira	VE MP	C9064 C9386 P9715 P11709 2 C9715 C11107 P11715 P11716 C11704 C11709 P11759 P11761 C11711 C11713 P11852 P11854	2	2
Humira	VE MP	C9064 C9386 P9715 P11709 2 C9715 C11107 P11715 P11716 C11704 C11709 P11759 P11761 C11711 C11713 P11852 P11854 C11715 C11716 P11855 P12098 C11717 C11759 P12101 P12147	2	2
Humira	VE MP	C9064 C9386 P9715 P11709 2 C9715 C11107 P11715 P11716 C11704 C11709 P11759 P11761 C11711 C11713 P11852 P11854 C11715 C11716 P11855 P12098 C11717 C11759 P12101 P12147 C11761 C11767 P13602 P13609	2	2
Humira	VE MP	C9064 C9386 P9715 P11709 2 C9715 C11107 P11715 P11716 C11704 C11709 P11759 P11761 C11711 C11713 P11852 P11854 C11715 C11716 P11855 P12098 C11717 C11759 P12101 P12147 C11761 C11767 P13602 P13609 C11852 C11853	2	2
Humira	VE MP	C9064 C9386 P9715 P11709 2 C9715 C11107 P11715 P11716 C11704 C11709 P11759 P11761 C11711 C11713 P11852 P11854 C11717 C11759 P11855 P12098 C11717 C11759 P12101 P12147 C11761 C11767 P13602 P13609 C11852 C11853 C11854 C11855	2	2
Humira	VE MP	C9064 C9386 P9715 P11709 2 C9715 C11107 P11715 P11716 C11704 C11709 P11759 P11761 C11711 C11713 P11852 P11854 C11717 C11759 P12101 P12147 C11761 C11767 P13602 P13609 C11852 C11853 C11854 C11855 C11861 C11865	2	2
Humira	VE MP	C9064 C9386 P9715 P11709 2 C9715 C11107 P11715 P11716 C11704 C11709 P11759 P11761 C11711 C11713 P11852 P11854 C11717 C11759 P12101 P12147 C11761 C11767 P13602 P13609 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903	2	2
Humira	VE MP	C9064 C9386 P9715 P11709 2 C9715 C11107 P11715 P11716 C11704 C11709 P11759 P11761 C11711 C11713 P11852 P11854 C11717 C11769 P12101 P12147 C11761 C11767 P13602 P13609 C11852 C11853 C11854 C11855 C11867 C11903 C11906 C11966	2	2
Humira	VE MP	C9064 C9386 P9715 P11709 2 C9715 C11107 P11715 P11716 C11704 C11709 P11759 P11761 C11711 C11713 P11852 P11854 C11717 C11767 P11855 P12098 C11717 C11767 P13602 P13609 C11852 C11853 C11854 C11855 C11867 C11903 C11906 C11966 C12098 C12101	2	2
Humira	VE MP	C9064 C9386 P9715 P11709 2 C9715 C11107 P11715 P11716 C11704 C11709 P11759 P11761 C11711 C11713 P11852 P11854 C11717 C11759 P11855 P12098 C11717 C11767 P13602 P13609 C11852 C11853 C11854 C11855 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123	2	2
Humira	VE MP	C9064 C9386 P9715 P11709 2 C9715 C11107 P11715 P11716 C11704 C11709 P11755 P11761 C11711 C11713 P11852 P11854 C11715 C11716 P11855 P12098 C11717 C11767 P12101 P12147 C11761 C11767 P13602 P13609 C11852 C11853 C11854 C11855 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148	2	2
Humira	VE MP	C9064 C9386 P9715 P11709 2 C9715 C11107 P11715 P11716 C11704 C11709 P11759 P11761 C11711 C11713 P11852 P11854 C11715 C11716 P11855 P12098 C11717 C11759 P12101 P12147 C11761 C11767 P13602 P13609 C11852 C11853 C11854 C11855 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156	2	2
Humira	VE MP	C9064 C9386 P9715 P11709 2 C9715 C11107 P11715 P11716 C11704 C11709 P11759 P11761 C11711 C11713 P11852 P11854 C11715 C11716 P11855 P12098 C11717 C11759 P12101 P12147 C11761 C11767 P13602 P13609 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158	2	2
Humira	VE MP	C9064 C9386 P9715 P11709 P11715 C11704 C11709 P11715 P11716 P11715 P11716 P11715 P11716 P11715 C11711 C11713 P11852 P11854 C11717 C11759 P12101 P12147 C11761 C11767 P13602 P13609 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189	2	2
Humira	VE MP	C9064 C9386 P9715 P11709 2 C9715 C11107 P11715 P11716 C11704 C11709 P11759 P11761 C11711 C11713 P11852 P11854 C11715 C11716 P11855 P12098 C11717 C11759 P12101 P12147 C11761 C11767 P13602 P13609 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158	2	2

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Yuflyma	EW MF	IP	C9064 C9386	P9715 P11709	2	2	2
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			C14656 C14662					
			C14670 C14672					
			C14673 C14683					
			C14701 C14713					
			C14730					
Humira	VE	MP	C9064 C9386	P9064 P9386	2	3	2	
пинна	٧L	IVIP			2	3	2	
			C9715 C11107	P11861 P12174				
			C11704 C11709					
			C11711 C11713					
			C11715 C11716	P13694 P14483				
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			C14662 C14670					
			C14713 C14730					
Yuflyma	EW	MP	C9064 C9386	P9064 P9386	2	3	2	
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				P12194 P13599				
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			C11604 C11606					
			C11631 C11635					
			C11704 C11709					
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			C11715 C11716					
			C11717 C11718					
			C11759 C11761	P14673				
			C11767 C11852					
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			C11966 C12098 C12101 C12122					
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			C14673 C14683					
			C14701 C14713					
			C14730					
Humira	VE	MP	C9064 C9386	P11107 P12155	2	4	2	
Hullilla	٧L	IVII	C9715 C11107	P12212 P13556	2	4	2	
				P13612 P14377				
			C11711 C11713					
			C11715 C11716					
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			C11761 C11767					
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			C12275 C12315					
			C12336 C13556					
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			C13650 C13681					
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			C14499 C14507					
			C14655 C14656					
			C14662 C14670					
			3 : :002 0 : 107 0					

			C14713 C14730				
Yuflyma	EW MF	Р	C9064 C9386	P11107 P12155	2	4	2
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			C11855 C11861				
			C11865 C11867				
			C11903 C11906				
			C11966 C12098				
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				C11761 C11767	P12148 P12156				
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				C14486 C14488					
				C14493 C14498					
				C14499 C14507					
				C14499 C14307 C14655 C14656					
				C14662 C14670					
				C14002 C14070 C14713 C14730					
				014/13/014/30					
			MP	C14107 C14136		2	5	2	C(100)
	Yuflyma	EW	MP	C9064 C9386	P11523 P11524	2	5	2	
	. anymu	_ * *		C9715 C11107	P11579 P11604	_	J	_	
				C11523 C11524	P11606 P11631				
1				011020 011024	1 11000 F 11031				

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C11529 C11579 P11635 P11704
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           C14673 C14683
           C14701 C14713
          C14730
MP
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           C14107 C14136
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Humira	VE	MP	C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11906 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12274 C12272 C12273 C12275 C12315 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14477 C14478 C14488 C14493 C14488 C14493 C14498 C144655 C14656 C146662 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				ŀ
		C11759 C11761				ŀ
		C11767 C11852				ŀ
		C11853 C11854				ŀ
		C11855 C11861				ŀ
		C11865 C11867				ŀ
		C11903 C11906				ŀ
		C11966 C12098				ļ
		C12101 C12122				ļ
		C12123 C12147				ļ
		C12148 C12155				Į.
		C12156 C12157				ŀ
		C12158 C12174				ŀ
		C12189 C12174				ŀ
		C12194 C12212				ŀ
		C12214 C12228				ŀ
		C12240 C12272				ŀ
		C12273 C12275				ŀ
		C12273 C12273				ŀ
		C12515 C12556 C13556 C13599				ŀ
		C13602 C13609				ŀ
		C13612 C13650				ŀ
		C13612 C13694				ŀ
		C13081 C13094 C14377 C14378				ŀ
		C14377 C14376 C14483 C14486				ļ
		C14488 C14493				ļ
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		C14496 C14498 C14499 C14507				ļ
		C14499 C14507 C14567 C14568				ŀ
		C14590 C14655				ŀ
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		C14656 C14662				ŀ
		C14670 C14672				ŀ
		C14673 C14683				ŀ
		C14701 C14713				ŀ
		C14730				ŀ
Humira	VE MP	C9064 C9386	P12272 P12315 4	5	2	
i iuillia	V L IVIF	C9715 C11107	F122/2 F12313 4	ວ	4	ļ
		C11704 C11709				ļ
		C11704 C11709 C11711 C11713				ļ
		C11711 C11713				ļ
						ŀ
		C11717 C11759				ŀ
		C11761 C11767				

		C11852 C11853					
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		C11867 C11903					
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		C12098 C12101					
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		C12122 C12123 C12147 C12148					
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		C12275 C12315					
		C12336 C13556					
		C13599 C13602					
		C13609 C13612					
		C13650 C13681					
		C13694 C14377					
		C14378 C14483					
		C14486 C14488					
		C14493 C14498					
		C14499 C14507					
		C14655 C14656					
		C14662 C14670					
		C14002 C14070 C14713 C14730					
		C147 13 C14730					
V61	EW MP	00004 00000	P11529 P12272	4	5	0	
Yuflyma	EVV IVIP	C9064 C9386		4	5	2	
		C9715 C11107	P12315				
		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 C12174				
		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				
		014730				
Humira	VE MP	C9064 C9386 P	9715 P11709	6	0	2
Tullilla	V L IVII		P11715 P11716	U	U	2
			P11759 P11761			
		C11704 C11709 P				
		C11715 C11716 P				
		C11717 C11759 P				
		C11761 C11767 P				
		C11852 C11853 P	13602 P13609			
		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				
		C13094 C14377 C14378 C14483				
		C14486 C14488				
		C14493 C14498				
		C14499 C14507				
		C14499 C14507 C14655 C14656				
		C14662 C14670				
		C14713 C14730				
Yuflyma	EW MP	C9064 C9386	P9715 P11709	6	0	2
Tullyllia	LVV IVIF	C9715 C11107	P11715 P11716	O	U	2
			P11759 P11761			
			P11852 P11854			
			P11855 P12098			
			P12101 P12147			
			P12275 P12336			
			P13602 P13609			
		C11711 C11713 C11715 C11716				
		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					
					C14499 C14507 C14567 C14568					
					C14590 C14655					
					C14656 C14662					
					C14670 C14672					
					C14673 C14683					
					C14701 C14713					
					C14730					
Injection 40 mg in 0.4 mL pre-	Injection	Humira	VE	MP	See Note 3	See Note 3	See Note	See Note	2	C(100)
filled syringe	•						3	3		, ,
		Yuflyma	EW	MP	See Note 3	See Note 3	See Note	See Note	2	C(100)
		, ,					3	3		- (/
							· ·	•		
		Humira	VE	MP	C9064 C9386	P11713	2	0	2	
		Hamila	V L	IVII	C9715 C11107	1 11/13	2	O	_	
					C11704 C11709					
					C11711 C11713					
					C11715 C11716					
					C11717 C11759					
					C11761 C11767					
					C11852 C11853					
					C11854 C11855					
					C11861 C11865					
					C11867 C11903					
					C11906 C11966					
					C12098 C12101					
					C12096 C12101					
					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	P11713	2	0	2	
Tullyllia	LVV IVIE	C9715 C11107	F11/13	2	U	2	
		C11523 C11524					
		C11579 C11604					
		C11606 C11631					
		C11635 C11704					
		C11709 C11711					
		C11713 C11711					
		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 C12179 C12194 C12190 C12194 C12212 C12214 C12228 C12240					

		C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14730					
Humira	VE MP	C9715 C11107 F	P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147	2	2	2	

			C14488 C14493				
			C14498 C14499				
			C14507 C14655				
			C14656 C14662				
			C14670 C14713				
			C14730				
Yuflyma	EW	MP	C9064 C9386	P9715 P11709	2	2	2
•			C9715 C11107	P11715 P11716			
				P11759 P11761			
				P11852 P11854			
			C11606 C11631	P11855 P12098			
				P12101 P12147			
				P13602 P13609			
			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				
			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				
		45	00004 00000	D0004 D0000	•		•
Humira	VE N	/IP	C9064 C9386	P9064 P9386	2	3	2
			C9715 C11107	P11861 P12174			
			C11704 C11709	P12194 P13599			
			C11711 C11713	P13650 P13681			
			C11715 C11716	P13694 P14483			
			C11717 C11759				
			C11761 C11767	P14498 P14655			
			C11761 C11767 C11852 C11853				
				F 14002 P 140/U			
			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				
			C14377 C14378 C14483 C14486				
			C14488 C14493				
			C14498 C14499				
			C14507 C14655				
			C14656 C14662				
			C14670 C14713				
			C14730				
Yuflyma	EW N	/IP	C9064 C9386	P9064 P9386	2	3	2
ranyina	_ v v 1v	v 11	C9715 C11107	P11861 P12174	_	5	-
			C11523 C11524				
				P12194 P13599			
			C11579 C11604	P13650 P13681			
			C11606 C11631	P13694 P14483			

		C11635 C11704	P14486 P14488		
		C11709 C11711	P14496 P14498		
		C11713 C11715	P14568 P14590		
		C11716 C11717	P14655 P14662		
		C11718 C11759	P14670 P14672		
		C11761 C11767	P14673		
		C11852 C11853			
		C11854 C11855			
		C11861 C11865			
		C11867 C11903			
		C11906 C11966			
		C12098 C12101			
		C12122 C12123			
		C12147 C12148			
		C12155 C12156			
		C12157 C12158			
		C12174 C12189			
		C12190 C12194			
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		C12228 C12240			
		C13556 C13599			
		C13602 C13609			
		C13612 C13650			
		C13681 C13694			
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		C14567 C14568			
		C14590 C14655			
		C14656 C14662			
		C14670 C14672			
		C14673 C14683			
		C14701 C14713			
		C14730			
Humira	VE MP	C9064 C9386	P11107 P12155 2	4	2
ııuııııa	V L IVIF	C9064 C9366 C9715 C11107	P11107 P12155 2 P12212 P13556	4	۷
		C11704 C11709	P13612 P14377		
		C11711 C11713			
		C11711 C11713	1 14070		
		C11713 C11710			
		C11717 C11759			
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		C11852 C11853					
		C11854 C11855					
		C11861 C11865					
		C11867 C11903					
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		C12098 C12101					
		C12147 C12148					
		C12155 C12156					
		C12157 C12158					
		C12174 C12189					
		C12190 C12194					
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		C12228 C12240					
		C13556 C13599					
		C13602 C13609					
		C13612 C13650					
		C13681 C13694					
		C14377 C14378					
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		C14488 C14493					
		C14498 C14499					
		C14507 C14655					
		C14656 C14662					
		C14670 C14713					
		C14730					
		C14730					
Yuflyma	EW MP	C9064 C9386	P11107 P12155	2	4	2	
rullyllia	EVV IVIE			2	4	2	
		C9715 C11107	P12212 P13556				
			P13612 P14377				
		C11579 C11604					
		C11606 C11631					
		C11635 C11704					
		C11709 C11711					
		C11713 C11715					
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		C11718 C11759					
		C11761 C11767					
		C11852 C11853					
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		C12122 C12123			
		C12147 C12148			
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		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			
		014730			
Humira	VE MP	C9064 C9386 P11704 P11711	2 5	2	
пинна	VE IVIE		2 3	2	
		C9715 C11107 P11717 P11767			
		C11704 C11709 P11853 P11865			
		C11711 C11713 P11867 P11903			
		C11715 C11716 P11906 P11966			
		C11717 C11759 P12122 P12123			
		C11761 C11767 P12148 P12156			
		C11852 C11853 P12157 P12158			
		C11854 C11855 P12189 P12190			
		C11861 C11865 P12214 P12228			
		C11867 C11863 P12214 P12226 C11867 C11903 P12240 P14493			
		C11906 C11966 P14499 P14507			
		C12098 C12101 P14656 P14713			
		C12122 C12123 P14730			
		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					
				014700					
			MP	C14107 C14136		2	5	2	C(100)
	Yuflyma	EW	MP	C9064 C9386	P11523 P11524	2	5	2	
	•			C9715 C11107	P11579 P11604				
				C11523 C11524	P11606 P11631				
				C11579 C11604	P11635 P11704				
				C11606 C11631	P11711 P11717				
				C11635 C11704					
				C11709 C11711	P11853 P11865				
				C11713 C11715					
				C11716 C11717	P11906 P11966				
				C11718 C11759	P12122 P12123				
				C11761 C11767	P12148 P12156				
				C11852 C11853	P12157 P12158				
				C11854 C11855	P12189 P12190				
				C11861 C11865	P12214 P12228				
				C11867 C11903	P12240 P14493				
					P14499 P14507				
				C12098 C12101					
				C12122 C12123					
				C12147 C12148					
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				C12174 C12189					
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C14590 C14655		
C14656 C14662		
C14670 C14672		
C14673 C14683		
C14701 C14713		
C14730		
MP C14107 C14136 2 5	2	C(100)
Humira VE MP C9064 C9386 P9715 P11709 6 0	2	
C9715 C11107 P11716		
C11704 C11709 P11759 P11761		
C11711 C11713 P11852 P11854		
C11715 C11716 P11855 P12098		
C11717 C11759 P12101 P12147		
C11761 C11767 P13602 P13609		
C11852 C11853		
C11854 C11855		
C11861 C11865		
C11867 C11903		
C11906 C11966		
C12098 C12101		
C12122 C12123		
C12147 C12148		
C12155 C12156		
C12157 C12158		
C12174 C12189		
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C12228 C12240		
C13556 C13599		
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			C14507 C14655				
			C14656 C14662				
			C14670 C14713				
			C14730				
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Yuflyma	EW	MP	C9064 C9386	P9715 P11709	6	0	2
			C9715 C11107	P11715 P11716			
			C11523 C11524	P11759 P11761			
			C11579 C11604	P11852 P11854			
			C11606 C11631	P11855 P12098			
				P12101 P12147			
				P13602 P13609			
			C11713 C11715	1 100021 10000			
			C11716 C11717				
			C11718 C11759				
			C11761 C11767				
			C11852 C11853				
			C11854 C11855				
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			C12212 C12214				
			C12228 C12240				
			C13556 C13599				
			C13602 C13609				
			C13612 C13650				
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			C14496 C14498				
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			C14567 C14568				
			C14590 C14655				
			C14656 C14662				

					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 C12148 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					
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			C14701 C14713					
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Hadlima	RF	MP	C9064 C9386	P11713	2	0	2	
		•••	C9715 C11107		_	· ·	_	
			C11523 C11524					
			C11529 C11579					
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		C14673 C14683				
		C14701 C14713				
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Hurimoz	SZ MP	C9064 C9386 P11713	2	0	2	
Hyrimoz	SZ IVIF	C9715 C11107	2	U	2	
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			C12158 C12174				
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			C12240 C12272				
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			C13602 C13609				
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			C14377 C14378				
			C14483 C14486				
			C 14403 C 14400				

		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 C11717 C11713 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 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378	6 1 4 8 7 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	C11604 C11606 C11631 C11635 C11704 C11709	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					
I f	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	3				
		C12157 C12158					
		C12174 C12189					
		C12190 C12194					
		C12190 C12194					
		C12228 C12240					
		C13556 C13599					
		C13602 C13609					
		C13612 C13650					
		C13681 C13694	ļ				
		C14377 C14378	3				
		C14483 C14486					
		C14488 C14493					
		C14496 C14498					
		C14499 C14507					
		C14499 C14568					
		C14590 C14655					
		C14656 C14662					
		C14670 C14672					
		C14673 C14683					
		C14701 C14713	3				
		C14730					
Hadlima	RF MP	C9064 C9386	P11713	2	0	2	
		C9715 C11107					
		C11523 C11524	ļ				
		C11579 C11604	Į.				
		C11606 C11631					
		C11635 C11704					
		C11709 C11711					
		C11709 C11711					
		C11713 C11713					
		C11718 C11759					
		C11761 C11767					
		C11852 C11853					
		C11854 C11855					
		C11861 C11865	5				
		C11867 C11903					
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		C12098 C12101					
		C12122 C12123					
		C12147 C12148					
		O404EE O404E6					
		C12155 C12156 C12157 C12158					

		C12174 C12189				
		C12190 C12194				
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		C12228 C12240				
		C13556 C13599				
		C13602 C13609				
		C13612 C13650				
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		C14567 C14568				
		C14590 C14655				
		C14656 C14662				
		C14670 C14672				
		C14673 C14683				
		C14073 C14083 C14701 C14713				
		C14730				
Lib milion and	07 MD	00004 00000 D44740	0	0	0	
Hyrimoz	SZ MP	C9064 C9386 P11713	2	0	2	
		C9715 C11107				
		C11523 C11524				
		C11523 C11524 C11579 C11604				
		C11523 C11524 C11579 C11604 C11606 C11631				
		C11523 C11524 C11579 C11604				
		C11523 C11524 C11579 C11604 C11606 C11631				
		C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711				
		C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715				
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		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 C11906 C12098 C12101 C12122 C12123				
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		C12212 C12214					
		C12228 C12240					
		C13556 C13599					
		C13602 C13609					
		C13612 C13650					
		C13681 C13694					
		C13001 C13094 C14377 C14378					
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		C14673 C14683					
		C14701 C14713					
		C14730					
Idacio	PK MP	C9064 C9386 P117	10	2	0	2	
Idacio	PK IVIP	C9004 C9300 P117	13	2	0	2	
		C97 13 C 1 1 1 U 7					
		C11523 C11524					
		C11523 C11524 C11579 C11604					
		C11523 C11524 C11579 C11604 C11606 C11631					
		C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704					
		C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711					
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		C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865					
		C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855					
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		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					
		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					
		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					
		C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148					
		C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11717 C11718 C11777 C11718 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156					
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			C13556 C13599				
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			C13612 C13650				
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			C14670 C14672				
			C14673 C14683				
			C14073 C14003 C14701 C14713				
			C14701 C14713				
			C14730				
Amgevita	XT M	ИΡ	C9064 C9386	P9715 P11709	2	2	2
Angevila	/\	VII	C9715 C11107	P11715 P11716	_	_	_
			C11523 C11524	P11759 P11761			
				P11852 P11854			
				P11855 P12098			
				P12101 P12147			
				P13602 P13609			
			C11709 C11711 C11713 C11715	F 13002 F 13009			
			C11713 C11713				
			C11718 C11717				
			C11716 C11759 C11761 C11767				
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			C11854 C11855				
			C11861 C11865				
			C11867 C11903				
			C11906 C11966				
			C12098 C12101				
			C12122 C12123				
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			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 C14650 C14655 C14656 C14662 C14670 C14672
		C14673 C14683 C14701 C14713 C14730
Hadlima	RF MP	C9064 C9386 P9715 P11709 2 2 2 2 C9715 C11107 P11715 P11716 C11523 C11524 P11759 P11761 C11579 C11604 P11852 P11854 C11606 C11631 P11855 P12098 C11635 C11704 P12101 P12147 C11709 C11711 P13602 P13609 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C1210 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 P9715 P11709 2 2 2 C9715 C11107 P11715 P11716 C11523 C11524 P11759 P11761 C11579 C11604 P11852 P11854 C11606 C11631 P11855 P12098 C11635 C11704 P12101 P12147 C11709 C11711 P13602 P13609 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 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 P9715 P11709 2 2 C9715 C11107 P11715 P11716 C11523 C11524 P11759 P11761 C11579 C11604 P11852 P11854 C11606 C11631 P11855 P12098 C11635 C11704 P12101 P12147 C11709 C11711 P13602 P13609 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C1222 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14483 C14486 C14488 C14493 C14496 C14498	2

				C14499 C14507					
				C14567 C14568					
				C14590 C14655					
				C14656 C14662					
				C14670 C14672					
				C14673 C14683					
				C14701 C14713					
				C14730					
	Amgevita	XT	MP		P9064 P9386	2	3	2	
					P11861 P12174				
					P12194 P13599				
				C11579 C11604					
				C11606 C11631					
				C11635 C11704					
				C11709 C11711					
				C11713 C11715					
				C11716 C11717					
				C11718 C11759					
				C11761 C11767	P14673				
				C11852 C11853					
				C11854 C11855					
				C11861 C11865					
				C11867 C11903					
				C11906 C11966					
				C12098 C12101 C12122 C12123					
				C12122 C12123 C12147 C12148					
				C12147 C12146 C12155 C12156					
				C12155 C12156 C12157 C12158					
				C12174 C12189					
				C12174 C12169 C12190 C12194					
				C12212 C12214					
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				C13556 C13599					
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				C13681 C13694					
				C14377 C14378					
				C14483 C14486					
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				C14496 C14498					
				C14499 C14507					
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		C, C, C,	14590 C14655 14656 C14662 14670 C14672 14673 C14683 14701 C14713 14730					
Hadlima	RF MI	ૹ ૽ઌ૽ઌ૽ઌ૽ઌ૽ઌ૽ઌ૽ઌ૽ઌ૽ઌ૽ઌ૽ઌ૽ઌ૽ઌ૽ઌ૽ઌ૽ઌ૽ઌ૽ઌ૽ઌ	11579 C11604 11606 C11631 11635 C11704 11709 C11711 11713 C11715 11716 C11717	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14675 P14672 P14673	2	3	2	

			C14670 C14672					
			C14673 C14683					
			C14701 C14713					
			C14730					
Hyrimoz	SZ	MP	C9064 C9386	P9064 P9386	2	3	2	
,			C9715 C11107	P11861 P12174				
				P12194 P13599				
				P13650 P13681				
				P13694 P14483				
				P14486 P14488				
				P14496 P14498				
				P14568 P14590				
				P14655 P14662				
				P14670 P14672				
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			C11852 C11853 C11854 C11855					
			C11861 C11865					
			C11867 C11903					
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			C12122 C12123					
			C12147 C12148					
			C12155 C12156					
			C12157 C12158					
			C12174 C12189					
			C12190 C12194					
			C12212 C12214					
			C12228 C12240					
			C13556 C13599					
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			C14496 C14498					
			C14499 C14507					
			C14499 C14507 C14567 C14568					
			C14590 C14655					
			C14656 C14662					
			C14670 C14672					
			C14673 C14683					

C14701 C14713 C14720 Idacio PK MP C9064 C9386 C9715 C11107 C1152 C3 C11524 P11851 P12714 C11579 C11060 C11670 C11079 C11579 C115								
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Amgevita	XT	MP	C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11703 C11715 C11713 C11715 C11716 C11717 C11718 C11776 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11906 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12148 C12125 C12123 C12147 C12148 C12122 C1213 C12147 C12148 C12122 C1213 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 C14499 C14507 C14567 C14568 C14590 C14655 C14666 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730	P14378	2	4	2
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		C11709 C11711			
		C11713 C11715			
		C11716 C11717			
		C11718 C11759			
		C11761 C11767			
		C11852 C11853			
		C11854 C11855			
		C11861 C11865			
		C11867 C11903			
		C11906 C11966			
		C12098 C12101			
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		C12155 C12156			
		C12157 C12158			
		C12174 C12189			
		C12190 C12194			
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		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			
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Hyrimoz	SZ MP	C9064 C9386	P11107 P12155 2	4	2
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		C11713 C11715				
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		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				
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		C14590 C14655				
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		C14670 C14672				
		C14673 C14683				
		C14701 C14713				
		C14730				
Idacio	PK MP	C9064 C9386	P11107 P12155	2	4	2
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		C11606 C11631				
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			C14496 C14498				
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			C14567 C14568				
			C14507 C14508 C14590 C14655				
			C14590 C14655 C14656 C14662				
			C14670 C14672				
			C14673 C14683				
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Amgevita	XT N	MP	C9064 C9386	P11523 P11524	2	5	2
			C9715 C11107	P11579 P11604			
			C11523 C11524				
				P11635 P11704			
			C11606 C11631	P11711 P11717			
				P11718 P11767			
			C11709 C11711	P11853 P11865			
				P11867 P11903			

			C11716 C11717	P11906 P11966				
				P12122 P12123				
				P12148 P12156				
				P12157 P12158				
				P12189 P12190				
				P12214 P12228				
				P12240 P14493				
				P14499 P14507				
				P14567 P14656				
			C12122 C12123					
				P14713 P14730				
			C12155 C12156					
			C12157 C12158					
			C12174 C12189					
			C12190 C12194					
			C12212 C12214					
			C12228 C12240					
			C13556 C13599					
			C13602 C13609					
			C13612 C13650					
			C13681 C13694					
			C14377 C14378					
			C14483 C14486					
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			C14590 C14655					
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			C14673 C14683					
			C14701 C14713					
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			044407 044400		•	_		0(400)
		MP	C14107 C14136		2	5	2	C(100)
Hadlima	RF	MP	C9064 C9386	P11523 P11524	2	5	2	
Hadiiiia	131	IVII	C9004 C9380 C9715 C11107	P11579 P11604	_	5	_	
			C11523 C11524	P11606 P11631				
				P11635 P11704				
				P11711 P11717				
				P11718 P11767				
				P11853 P11865				
			C11/13 C11/15	P11867 P11903				

			C11716 C11717	P11906 P11966				
				P12122 P12123				
				P12148 P12156				
				P12157 P12158				
				P12189 P12190				
				P12214 P12228				
			C11867 C11903	P12240 P14493				
			C11906 C11966	P14499 P14507				
			C12098 C12101	P14567 P14656				
			C12122 C12123					
				P14713 P14730				
			C12155 C12156	1 147 101 14700				
			C12157 C12158					
			C12174 C12189					
			C12190 C12194					
			C12212 C12214					
			C12228 C12240					
			C13556 C13599					
			C13602 C13609					
			C13612 C13650					
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			C14590 C14655					
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			C14670 C14672					
			C14673 C14683					
			C14701 C14713					
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			000					
		MP	C14107 C14136		2	5	2	C(100)
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Hyrimoz	SZ	MP	C9064 C9386	P11523 P11524	2	5	2	
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			C11523 C11524	P11606 P11631				
				P11635 P11704				
				P11711 P11717				
				P11718 P11767				
				P11853 P11865				
			C11713 C11715	P11867 P11903				

			C11716 C11717	P11906 P11966				
				P12122 P12123				
				P12148 P12156				
				P12157 P12158				
				P12189 P12190				
				P12214 P12228				
				P12240 P14493				
				P14499 P14507				
				P14567 P14656				
			C12122 C12123	P14683 P14701				
				P14713 P14730				
			C12155 C12156					
			C12157 C12158					
			C12174 C12189					
			C12190 C12194					
			C12212 C12214					
			C12228 C12240					
			C13556 C13599					
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			C14590 C14655					
			C14656 C14662					
			C14670 C14672					
			C14673 C14683					
			C14701 C14713					
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			014700					
		MP	C14107 C14136		2	5	2	C(100)
		••••	011101 011100		_	· ·	_	3(100)
Idacio	PK	MP	C9064 C9386	P11523 P11524	2	5	2	
	-		C9715 C11107	P11579 P11604		-		
			C11523 C11524					
				P11635 P11704				
				P11711 P11717				
				P11718 P11767				
				P11853 P11865				
				P11853 P11865 P11867 P11903				
			G11/13/G11/15	F 11007 P 11903				

C11716 C11717 P11906 P11966 C11718 C11759 P12122 P12123 C11761 C11767 P12148 P12156 C11852 C11853 P12157 P12158 C11854 C11855 P12189 P12190 C11861 C11865 P12214 P12228 C11867 C11903 P12240 P14493 C11906 C11966 P14499 P14507 C12098 C12101 P14567 P14656 C12122 C12123 P14683 P14701 C12147 C12148 P14713 P14730	
C11718 C11759 P12122 P12123 C11761 C11767 P12148 P12156 C11852 C11853 P12157 P12158 C11854 C11855 P12189 P12190 C11861 C11865 P12214 P12228 C11867 C11903 P12240 P14493 C11906 C11966 P14499 P14507 C12098 C12101 P14567 P14656 C12122 C12123 P14683 P14701	
C11761 C11767 P12148 P12156 C11852 C11853 P12157 P12158 C11854 C11855 P12189 P12190 C11861 C11865 P12214 P12228 C11867 C11903 P12240 P14493 C11906 C11966 P14499 P14507 C12098 C12101 P14567 P14656 C12122 C12123 P14683 P14701	
C11852 C11853 P12157 P12158 C11854 C11855 P12189 P12190 C11861 C11865 P12214 P12228 C11867 C11903 P12240 P14493 C11906 C11966 P14499 P14507 C12098 C12101 P14567 P14656 C12122 C12123 P14683 P14701	
C11854 C11855 P12189 P12190 C11861 C11865 P12214 P12228 C11867 C11903 P12240 P14493 C11906 C11966 P14499 P14507 C12098 C12101 P14567 P14656 C12122 C12123 P14683 P14701	
C11861 C11865 P12214 P12228 C11867 C11903 P12240 P14493 C11906 C11966 P14499 P14507 C12098 C12101 P14567 P14656 C12122 C12123 P14683 P14701	
C11867 C11903 P12240 P14493 C11906 C11966 P14499 P14507 C12098 C12101 P14567 P14656 C12122 C12123 P14683 P14701	
C11906 C11966 P14499 P14507 C12098 C12101 P14567 P14656 C12122 C12123 P14683 P14701	
C12098 C12101 P14567 P14656 C12122 C12123 P14683 P14701	
C12098 C12101 P14567 P14656 C12122 C12123 P14683 P14701	
C12122 C12123 P14683 P14701	
C12147 C12146 F14713 F14730 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	
014730	
MP C14107 C14136 2 5 2	C(100)
IVII C14107 C14130 2 3 2	C(100)
Amgevita XT MP C9064 C9386 P9715 P11709 6 0 2	
C9715 C11107 P11716	
C11523 C11524 P11759 P11761	
C11579 C11604 P11852 P11854	
C11606 C11631 P11855 P12098	
C11635 C11704 P12101 P12147	
C11709 C11711 P13602 P13609	
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
		C12174 C12109 C12190 C12194
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		C12212 C12214 C12228 C12240
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		C13336 C13399 C13602 C13609
		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
Literations a	DE MD	00004 00000
Hadlima	RF MP	C9064 C9386 P9715 P11709 6 0 2
		C9715 C11107 P11715 P11716
		C11523 C11524 P11759 P11761
		C11579 C11604 P11852 P11854
		C11606 C11631 P11855 P12098
		C11635 C11704 P12101 P12147
		C11709 C11711 P13602 P13609
		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				
		C12130 C12134 C12212 C12214				
		C12228 C12240				
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		C13681 C13694				
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		C14499 C14507				
		C14567 C14568				
		C14590 C14655				
		C14656 C14662				
		C14670 C14672				
		C14673 C14683				
		C14701 C14713				
		C14730				
Hyrimoz	SZ MP	C9064 C9386	P9715 P11709	6	0	2
		C9715 C11107	P11715 P11716			
		C11523 C11524				
		C11579 C11604	P11852 P11854			
		C11606 C11631	P11855 P12098			
		C11635 C11704	P12101 P12147			
		C11709 C11711	P13602 P13609			
		C11713 C11715				
		C11716 C11717				
		C11718 C11759				
		C11761 C11767				

			C11854 C11855				
			C11861 C11865				
			C11867 C11903				
			C11906 C11966				
			C12098 C12101				
			C12122 C12123				
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			C12147 C12146 C12155 C12156				
			C12157 C12158				
			C12174 C12189				
			C12190 C12194				
			C12212 C12214				
			C12228 C12240				
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			C14590 C14655				
			C14656 C14662				
			C14670 C14672				
			C14673 C14683				
			C14701 C14713				
			C14730				
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Idacio	PK MF	P	C9064 C9386	P9715 P11709	6	0	2
Iddolo	1 17 1711		C9715 C11107	P11715 P11716	· ·	Ü	_
			C11523 C11524	P11759 P11761			
			C11579 C11604	P11852 P11854			
				P11855 P12098			
				P12101 P12147			
			C11709 C11711				
				F 13002 P 13009			
			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				
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				C12228 C12240				
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				C14499 C14507				
				C14567 C14568				
				C14590 C14655				
				C14656 C14662				
				C14670 C14672				
				C14673 C14683				
				C14701 C14713				
				C14730				
Injection 80 mg in 0.8 mL pre-	Injection	Humira	VE MP	C11715 C11716	P12103 P12105	1	0	1
filled pen	•							
·				C11762 C11763	P14398 P14399			
				C11852 C11854				
				C11855 C12103				
				C12105 C12152				
				C12155 C12212				
				C12229 C12273				
				C12275 C12278				
				C12306 C14398				
				C14399				
			MP	C11715 C11716	P12273	2	2	1
				C11759 C11761				
				C11762 C11763				
				C11852 C11854				

				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	P11762 P11763 P11852 P11854 P11855 P12152 P12229 P12275	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		1	0	1

MP	C11715 C11716 P12273 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12155 C12212 C12229 C12273 C12275 C12278 C12306 C14398 C14399	2	2	1
MP	C11715 C11716 P12306 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12155 C12212 C12229 C12273 C12275 C12278 C12306 C14398 C14399	2	5	1
MP	C11715 C11716 P11715 P11 C11759 C11761 P11759 P11 C11762 C11763 P11762 P11 C11852 C11854 P11852 P11 C11855 C12103 P11855 P12 C12105 C12152 P12229 P12 C12155 C12212 P12229 P12 C12229 C12273 C12275 C12278 C12306 C14398 C14399	761 763 854 152	0	1

insert:

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

	(a)	calciferol omit:								
	(α)	omu.	а	Alendronate Plus D3 Sandoz	SZ M	MP NP	C6307 C6315 C6320	4	5	4
	(b)	omit from the column headed "Sch	edule Equivalent''	for the brand "Fo	samax P	Plus": a				
]		edule 1, Part 1, entry for Alendro calciferol	onic acid with co	olecalciferol in t	he form	n Tablet	70 mg (as alendron	ate sodium) wi	th 140 m	nicrograms
	(a)	omit:								
			а	Alendronate Plus D3 Sandoz	SZ M	MP NP	C6306 C6319 C6325	4	5	4
				C .1 1 1.0E	an Di	lus 70 ma	1/140 mca": a			
	(b)	omit from the column headed "Sche	edule Equivalent" j	tor the brand "Fos	samax Pi	ius /o mg	/170 mcg . u			
]	• •	omit from the column headed "Sche edule 1, Part 1, entry for Amisulp	-		samax Pi	ius 70 mg	7140 meg . u			
	• •	edule 1, Part 1, entry for Amisulp	-		samax Fi	ius 70 mg	7140 mcg . u			
l 	Sche	edule 1, Part 1, entry for Amisulp	-		WA M		C4246	60	5	60
	Sche	edule 1, Part 1, entry for Amisulp	oride in the form	Amisulpride 400 Winthrop	WA M	MP NP	C4246		5	60
]	Sche	edule 1, Part 1, entry for Amisulp	oride in the form	Amisulpride 400 Winthrop	WA M	MP NP	C4246		5	60
	Sche	edule 1, Part 1, entry for Amisulp	oride in the form	Amisulpride 400 Winthrop	WA M	MP NP nitriptyli	C4246		5	60 50
	Sche omit: Sche omit:	edule 1, Part 1, entry for Amisulp	a tyline in the form	Amisulpride 400 Winthrop Tablet contain Amitriptyline Alphapharm 25	WA M	MP NP nitriptyli	C4246 ne hydrochloride 25	mg 50	2	50
l	Sche omit: Sche	edule 1, Part 1, entry for Amisulp	tyline in the form	Amisulpride 400 Winthrop Tablet contain Amitriptyline Alphapharm 25 Capsule 500 mg	WA M ning am MQ M	MP NP nitriptyli MP NP	C4246 ne hydrochloride 25) [Maximum Quantit	mg 50	2	50

		a Blooms The Chemist Amoxicillin	BG MP NP		P10402	40 CN10402	0 CN10402	20
9]	Schedule 1, Part 1, entry for Amoxicillin in the fo	orm Powder for oral	suspension	250 mg (as trih	ydrate) per 5 r	nL, 100 m	ıL	
	insert in the column headed "Schedule Equivalent" (all	instances): a						
10]	Schedule 1, Part 1, entry for Amoxicillin							
	omit:							
	Powder for oral suspension Oral 250 mg (as trihydrate) per 5 mL, 100 mL (s19A)	Amoxicillin 250mg/ 5 ml Oral Suspension Sugar Free BP (Kent)	RQ PDP			1	0	1
11]	Schedule 1, Part 1, entry for Amoxicillin with clack clavulanic acid (as potassium clavulanate) [Maxinsert in the columns in the order indicated, and in alpha	ximum Quantity: 10; abetical order for the co	Number of F lumn headed	Repeats: 0] "Brand":				
11]	clavulanic acid (as potassium clavulanate) [Max	cimum Quantity: 10;	orm Tablet on Number of F	Repeats: 0]	ng amoxicillin			•
11]	clavulanic acid (as potassium clavulanate) [Max	abetical order for the con Blooms The Chemist Amoxicillin/Clavula	orm Tablet on Number of Following the Number of Following the Name of the Name	Repeats: 0] "Brand": C5832 C5893		(as trihye	drate) wi	th 125 mg
11]	clavulanic acid (as potassium clavulanate) [Max	abetical order for the constitution Blooms The Chemist Amoxicillin/Clavula nic Acid 875/125	orm Tablet of Number of Flumn headed BG MP NP PDP	Repeats: 0] 'Brand": C5832 C5893 C10413 C5833 C5894 containing 875 n	P5832 P5893	10 10	drate) wi	th 125 mg 10
	clavulanic acid (as potassium clavulanate) [Maxinsert in the columns in the order indicated, and in alpha Schedule 1, Part 1, entry for Amoxicillin with cla	abetical order for the constitution Blooms The Chemist Amoxicillin/Clavula nic Acid 875/125	Drm Tablet of Number of Polyment Tablet of Number of Numb	Repeats: 0] "Brand": C5832 C5893 C10413 C5833 C5894 containing 875 n	P5832 P5893	10 10	drate) wi	th 125 mg

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

omit from the column headed "Circumstances": C14438

(a)

- (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
	а	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
	а	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
	а	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
	а	B-Patch	IU	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
	а	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
	а	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
	а	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	а	B-Patch	IU	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		а	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		а	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		а	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		а	B-Patch	IU	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
		а	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
		а	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
		а	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 Tra	ansdermal a	B-Patch	IU		C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
	а	Bupredermal	TX		C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
	а	Buprenorphine Sandoz	SZ		C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
	а	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
	а	B-Patch	IU	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
	а	Bupredermal	TX	MP NP	C10748 C10752	P11753	4	0	2

			· <u> </u>				C10755 C11753					_
			а	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
			а	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
Schedule 1 substitute:	, Part 1, entry for Bupre	norphine in th	ne fo	orm Transderma	al pat	ch 20 mg	J					
	Transdermal patch 20 mg	Transdermal	а	B-Patch	IU	MP NP			2	0	2	
			а	Bupredermal	TX	MP NP			2	0	2	
			а	Buprenorphine Sandoz	SZ	MP NP			2	0	2	
			а	Norspan	MF	MP NP			2	0	2	
			а	B-Patch	IU	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
			а	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
			а	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
			а	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
	, Part 1, entry for Carbo	platin										
omit:												
				DBL Carboplatin	PF	MP			See Note 3	See Note 3	1 D	(100
	substitute: Schedule 1	Schedule 1, Part 1, entry for Carbo	Schedule 1, Part 1, entry for Carboplatin	Schedule 1, Part 1, entry for Buprenorphine in the fosubstitute: Transdermal patch 20 mg Transdermal a a a a Schedule 1, Part 1, entry for Carboplatin	Schedule 1, Part 1, entry for Buprenorphine in the form Transderma substitute: Transdermal patch 20 mg Transdermal a Bupredermal a Buprenorphine Sandoz a Norspan B-Patch a B-Patch	Schedule 1, Part 1, entry for Buprenorphine in the form Transdermal patsubstitute: Transdermal patch 20 mg Transdermal Transdermal Transdermal TX TX TX TX TX TX TX TX TX T	Schedule 1, Part 1, entry for Buprenorphine in the form Transdermal patch 20 mg substitute: Transdermal patch 20 mg Transdermal Transdermal patch 20 mg Transdermal Transdermal Transdermal Transdermal Transdermal TX MP NP Buprenorphine Sandoz A Norspan MF MP NP Bupredermal TX MP NP A Bupredermal TX MP NP Brandoz A Bupredermal Brandoz Bra	a Buprenorphine Sz MP NP C10748 C10752 C10755 C11753	Buprenorphine SZ MP NP C10748 C10752 P11753 P11	Buprenorphine SZ MP NP C10748 C10752 P11753 4	Buprenorphine Sandoz Augusta SZ MP NP C10748 C10752 P11753 Augusta A	Buprenorphine SZ MP NP C10748 C10752 P11753 4 0 2

[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 'substitute:	1, Part 1, entry for Certolize	ımab pegol								
Certolizu	mab pegol	Injection 200 mg in 1 mL single use pre-filled syringe	Injection	Cimzia	UC	MP	C9063 C9073 P10459 C9074 C9105 C9183 C9185 C9431 C9625 C10431 C10459 C10513 C11386 C12392 C14191 C14493 C14499 C14507 C14542 C14571 C14591 C14622 C14659 C14686 C14692 C14714	P12392 2	0	2	
						MP	C9063 C9073 P9185 F C9074 C9105 P14542 C9183 C9185 C9431 C9625 C10431 C10459 C10513 C11386 C12392 C14191 C14493 C14499 C14507 C14542 C14571 C14591 C14622 C14659 C14686 C14692 C14714		2	2	
						MP	C9063 C9073 P9063 F C9074 C9105 P9431 F C9183 C9185 P14493 C9431 C9625 P14507 C10431 C10459 C10513 C11386 C12392 C14191	P10431 P14499	5	2	

				C14493 C14499 C14507 C14542 C14571 C14591 C14622 C14659 C14686 C14692 C14714				
			MF	C9074 C9105 C9183 C9185 C9431 C9625	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 MF	C9063 C9073 C9074 C9105 C9183 C9185 C9431 C9625 C10431 C10459 C10513 C11386 C12392 C14191 C14493 C14499 C14507 C14542 C14571 C14591 C14686 C14659 C14714	P10459 P12392	2	0	2
			MF	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		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

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

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":

CYCLOPHOSPHA RQ MP MIDE-REACH	See Note See Note 1 3 3	PB(100)
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[26] Schedule 1, Part 1, entry for Dabigatran etexilate

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

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

	Schedule 1	, Part 1, omit entry for Estra , Part 1, entry for Etanercep		dydı	ogesterone								
formula w minerals		, Part 1, omit entry for Estra	diol with o	dydı	ogesterone								
ormula w	ith vitamins and												
	amino acids	Sachets containing oral powder C 12.5 g, 30 (EAA Supplement)	Oral		EAA Supplement	VF	MP NP	C4925 C4958		6	5	1	
30]	Schedule 1 substitute:	, Part 1, entry for Essential a	amino acio	ds f	ormula with vita	mins	and mir	nerals					
				а	ENTAC	LR	MP NP	C5037 C5044		60	5	30	D(100)
[29]	Schedule 1 omit:	, Part 1, entry for Entecavir	in the forn	n Ta	blet 1 mg (as m	onol	nydrate)						
20]	concentrate	e for I.V. infusion 500 mg in column headed "Circumstances	10 mL					206 C10509 C1	•	·	anu Solu	uon	
28]		erical order in the column heade , Part 1, entry for Durvaluma				ion d	onoontr	oto for LV infu	sion 120 mg	in 2.4 ml .	and Calu	tion	
27]		, Part 1, entry for Darolutam		,	" 044004								
				а	Pradaxa	BY	MP NP	C4269 C14308	P14308	120	5	60	
				а	PHARMACOR DABIGATRAN	CR	MP NP	C4269 C14308	P14308	120	5	60	
				а	Dabigatran Sandoz	SZ	MP NP	C4269 C14308	P14308	120	5	60	
				а	Pradaxa	BY	MP NP	C4269 C14308	P4269	60	5	60	
				а	PHARMACOR DABIGATRAN	CR	MP NP	C4269 C14308	P4269	60	5	60	

MP	C7289 C8839	P14508 P14509	2	1	1
	C8842 C8873	1 1 1000 1 1 1000	_	•	•
	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				
145	07000 00000	D0004 D0000	•		
MP	C7289 C8839	P9064 P9386	2	3	1
	C8842 C8873	P9388 P9473			
	C8879 C9064	P11107 P12164			
	C9081 C9123	P12261 P13532			
	C9140 C9162	P13533 P13538			
	C9377 C9380	P13593 P13598			
	C9386 C9388	P13646 P13647			
	C9473 C11107	P14382 P14427			
	C12164 C12261	P14483 P14486 P14488 P14498			
		P14488 P14498 P14513 P14552			
		P14553 P14554 P14576 P14577			
		P14600 P14655			
		P14662 P14670			
	C14493 C14498				
	C14499 C14507	1 17700			
	C14499 C14507 C14508 C14509				
	C 14500 C 14509				

					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 C14483 C14427 C14483 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14554 C14576 C14670 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	

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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
                RF MP
                                C7289 C8839
                                               P9064 P11107
                                                                       3
Brenzys
                                C8842 C8873
                                               P13532 P13533
                                C8879 C8887
                                               P13538 P13593
                                C8955 C9064
                                               P13598 P13646
                                C9081 C9123
                                               P13647 P14382
                                C9140 C9156
                                               P14427 P14483
                                C9162 C11107
                                               P14486 P14488
                                C13532 C13533
                                               P14498 P14581
                                C13538 C13593
                                               P14582 P14603
                                C13598 C13646
                                               P14655 P14662
                                C13647 C14382 P14670 P14671
                                C14427 C14483 P14673 P14703
                                C14486 C14488
                                C14493 C14498
                                C14499 C14507
                                C14581 C14582
                                C14603 C14629
                                C14655 C14656
                                C14662 C14670
                                C14671 C14673
                                C14683 C14701
                                C14703 C14713
                                C14715
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Enbrel	PF	MP	C13598 C13646 C13647 C14382 C14427 C14483	P14576 P14577 P14600 P14655 P14662 P14670	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 C14483 C14427 C14483 C144486 C144488 C14493 C14498 C14499 C14507 C14581 C14582 C14603 C14629 C14655 C14656	P14701 P14713	1	5	1

			D F	MD	C14662 C14670 C14671 C14673 C14683 C14701 C14703 C14713 C14715	D-2000 D0000		_		
		Enbrel		MP	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	
Injections 50 mg in 1 mL single	Injection	Enbrel		MP MP	C14154 C14155 See Note 3	See Note 3	1 See Note	5 See Note	1	C(100) C(100)
use pre-filled syringes, 4	injoodon				200 11010 0	200 11010 0	3	3	•	3(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					
Brenzys	RF	MP	C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703 C14713 C14715 C7289 C8839 C8842 C8873 C8879 C8887 C8955 C9064 C9081 C9123 C9140 C9156 C9162 C11107 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14482 C14427 C14483 C14448 C14448 C14499 C14507 C14581 C14582 C14603 C14629	P9064 P11107 P13532 P13533 P13538 P13593 P13598 P13646 P13647 P14482 P14427 P14483 P14486 P14488 P14498 P14581 P14582 P14603 P14655 P14662 P14670 P14671 P14673 P14703	1	3	1	
Enbrel	PF	MP	C14655 C14656 C14662 C14670 C14671 C14673 C14683 C14701 C14703 C14713 C14715 C7289 C8839	P9064 P9386	1	3	1	

		C8842 C8873	P9388 P9473				
		C8879 C9064	P11107 P12164				
		C9081 C9123	P12261 P13532				
		C9140 C9162	P13533 P13538				
		C9377 C9380	P13593 P13598				
		C9386 C9388	P13646 P13647				
		C9473 C11107					
			P14382 P14427				
		C12164 C12261					
		C13532 C13533					
			P14513 P14552				
			P14553 P14554				
			P14576 P14577				
			P14600 P14655				
		C14486 C14488	P14662 P14670				
		C14493 C14498	P14703				
		C14499 C14507					
		C14508 C14509					
		C14513 C14552					
		C14553 C14554					
		C14576 C14577					
		C14600 C14655					
		C14656 C14662					
		C14670 C14703					
		C14070 C14703					
		C14713 C14715					
Dron-1/0	RF MP	C7289 C8839	P7289 P8839	4	_	1	
Brenzys	KE IVIE			1	5	ı	
		C8842 C8873	P8842 P8873				
		C8879 C8887	P8879 P8887				
		C8955 C9064	P8955 P9081				
		C9081 C9123	P9123 P9140				
		C9140 C9156	P9156 P9162				
		C9162 C11107	P14493 P14499				
		C13532 C13533	P14507 P14629				
		C13538 C13593	P14656 P14683				
		C13598 C13646	P14701 P14713				
		C13647 C14382	P14715				
		C14427 C14483					
		C14486 C14488					
		C14493 C14498					
		C14499 C14507					
		C14581 C14582					
		C14501 C14502 C14603 C14629					
		C14603 C14629 C14655 C14656					
		C14662 C14670					

C8879 C9064 C9123 P9124 P9125 P9140 C9140 C9140 C9162 P9162 P9377 C9380 P9380 P14493 C9386 C9388 P14499 P14507 C9473 C11107 P14656 P14713 C12164 C12261 P14715 C13532 C13533 C13538 C13538 C13538 C13598 C13646 C13647 C14482 C14427 C14483 C14448 C14448 C14448 C14448 C14448 C14498 C14498 C14450 C14513 C14552 C14513 C14552	C9081 C9123 P9140 C9140 C9162 P9377 C9377 C9380 P9380 P14493 C9386 C9388 P14499 P14507 C9473 C11107 P14656 P14713 C12164 C12261 P14715 C13532 C13533 C13538 C13533 C13598 C13546 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552		C14553 C14554 C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703			
C8879 C9064 P8879 P9081 C9081 C9123 P9123 P9140 C9140 C9162 P9162 P9377 C9377 C9380 P9380 P14493 C9386 C9388 P14499 P14507 C9473 C11107 P14656 P14713 C12164 C12261 P14715 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488	C8842 C8873 P8842 P8873 C8879 C9064 P8879 P9081 C9081 C9123 P9123 P9140 C9140 C9162 P9162 P9377 C9377 C9380 P9380 P14493 C9386 C9388 P14499 P14507 C9473 C11107 P14656 P14713 C12164 C12261 P14715 C13532 C13533 C13538 C13598 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488		C14499 C14507 C14508 C14509 C14513 C14552			
C8879 C9064 P8879 P9081 C9081 C9123 P9123 P9140 C9140 C9162 P9162 P9377 C9377 C9380 P9380 P14493 C9386 C9388 P14499 P14507 C9473 C11107 P14656 P14713 C12164 C12261 P14715 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382	C8842 C8873 P8842 P8873 C8879 C9064 P8879 P9081 C9081 C9123 P9123 P9140 C9140 C9162 P9162 P9377 C9377 C9380 P9380 P14493 C9386 C9388 P14499 P14507 C9473 C11107 P14656 P14713 C12164 C12261 P14715 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382		C14486 C14488			
C8879 C9064 P8879 P9081 C9081 C9123 P9123 P9140 C9140 C9162 P9162 P9377 C9377 C9380 P9380 P14493 C9386 C9388 P14499 P14507 C9473 C11107 P14656 P14713 C12164 C12261 P14715 C13532 C13533	C8842 C8873 P8842 P8873 C8879 C9064 P8879 P9081 C9081 C9123 P9123 P9140 C9140 C9162 P9162 P9377 C9377 C9380 P9380 P14493 C9386 C9388 P14499 P14507 C9473 C11107 P14656 P14713 C12164 C12261 P14715 C13532 C13533		C13647 C14382			
C8879 C9064 P8879 P9081 C9081 C9123 P9123 P9140 C9140 C9162 P9162 P9377 C9377 C9380 P9380 P14493 C9386 C9388 P14499 P14507 C9473 C11107 P14656 P14713	C8842 C8873 P8842 P8873 C8879 C9064 P8879 P9081 C9081 C9123 P9123 P9140 C9140 C9162 P9162 P9377 C9377 C9380 P9380 P14493 C9386 C9388 P14499 P14507 C9473 C11107 P14656 P14713		C13532 C13533	P 14/15		
C8879 C9064 P8879 P9081 C9081 C9123 P9123 P9140 C9140 C9162 P9162 P9377 C9377 C9380 P9380 P14493	C8842 C8873 P8842 P8873 C8879 C9064 P8879 P9081 C9081 C9123 P9123 P9140 C9140 C9162 P9162 P9377 C9377 C9380 P9380 P14493		C9473 C11107	P14656 P14713		
C8879 C9064 P8879 P9081	C8842 C8873 P8842 P8873 C8879 C9064 P8879 P9081		C9140 C9162 C9377 C9380	P9162 P9377 P9380 P14493		
			C8879 C9064	P8879 P9081		

substitute:

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

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

substitute:

	Lozenge 800 microç citrate)	grams (as	Buccal	Actiq	ТВ	MP NP	C5904		60	0	30	
5]	Schedule 1, Part 1, entry fo	r Fentany	d .									
	omit:											
	Lozenge 1200 micro citrate)	ograms (as	Buccal	Actiq	ТВ	MP NP	C5904 C5915	P5915	9	0	9	
						MP NP	C5904 C5915	P5904	60	0	30	
	Lozenge 1600 micro citrate)	ograms (as	Buccal	Actiq	ТВ	MP NP	C5904 C5915	P5915	9	0	9	
						MP NP	C5904 C5915	P5904	60	0	30	
86]	Schedule 1, Part 1, entry fo substitute:	r Fentany	l in the forr	n Tablet (orally d	isintegra	ating) 40	0 micrograms	(as citrate)				
	Tablet (orally disinte	egrating)	Buccal	Fentora	ТВ	MP NP	C6027		56	0	28	
	400 micrograms (as		Duccai	rentora	10	IVII IVI	00021		00			
37]		s citrate)						(as citrate)				
3 7]	400 micrograms (as Schedule 1, Part 1, entry fo	er Fentany						(as citrate)	56	0	28	
	Schedule 1, Part 1, entry fo substitute: Tablet (orally disintered)	er Fentany egrating) s citrate)	I in the form	m Tablet (orally di	isintegra	ating) 60	0 micrograms C6027	,		0		
37] 38]	400 micrograms (as Schedule 1, Part 1, entry fo substitute: Tablet (orally disinte 600 micrograms (as	er Fentany egrating) s citrate)	I in the form	m Tablet (orally di	isintegra	ating) 60	0 micrograms C6027	,		0		
	400 micrograms (as Schedule 1, Part 1, entry fo substitute: Tablet (orally disinte 600 micrograms (as Schedule 1, Part 1, entry fo	egrating) or Fentany egrating) or Fentany egrating)	I in the form	m Tablet (orally di	isintegra	ating) 60	0 micrograms C6027	,		0		
	Schedule 1, Part 1, entry fo substitute: Tablet (orally disinte 600 micrograms (as Schedule 1, Part 1, entry fo substitute: Tablet (orally disinte for substitute:	egrating) or Fentany egrating) or Fentany egrating) egrating) ecitrate)	Buccal Buccal Buccal	Fentora Fentora Fentora	TB isintegra	MP NP ating) 80	0 micrograms C6027 0 micrograms C6027	(as citrate)	56 56		28	
88]	400 micrograms (as Schedule 1, Part 1, entry fo substitute: Tablet (orally disinte 600 micrograms (as Schedule 1, Part 1, entry fo substitute: Tablet (orally disinte 800 micrograms (as	egrating) or Fentany egrating) or Fentany egrating) egrating) ecitrate)	Buccal Buccal Buccal	Fentora Fentora Fentora	TB isintegra	MP NP ating) 80	0 micrograms C6027 0 micrograms C6027	(as citrate)	56 56		28	

				C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696				
[40]	Schedule 1, Part 1, entry for Filgrastim <i>omit:</i>							
	Injection 300 micrograms in 1 mL Injection	Neupogen	AN MP	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671	20	11	10	D(100)
				C8674 C8673 C8674 C8696				
[41]	Schedule 1, Part 1, entry for Filgrastim in the f	orm Injection 480 r	micrograms ir	C8672 C8673 C8674 C8696	illed syringe			
[41]		orm Injection 480 r	micrograms ir	C8672 C8673 C8674 C8696	illed syringe	11	10	D(100)
[41]				C8672 C8673 C8674 C8696 0.5 mL single-use pre-f C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673		11	10	D(100)

F 403	Only delta A. Donald and the few Electrons will be the few			. 50	C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696				
[43]	Schedule 1, Part 1, entry for Fluorouracil in the fo <i>omit</i> :	rm injection 2500	mg II	1 50 ML					
		DBL Fluorouracil Injection BP	PF	MP	C6266 C6297	See Note	See Note	1	D(100)
[44]	Schedule 1, Part 1, entry for Golimumab substitute:								
Golimuma	Injection 50 mg in 0.5 mL single Injection use pre-filled pen	Simponi	JC	MP	C9063 C9064 P9069 P9153 P9155 C9153 C9155 P9429 P10436 P10515 P11430 P10515 P11430 P14626 P14650 C14626 C14692 P10699 P10	3 7 5	3	1	
				MP	C9063 C9064 P9063 P9105 C9069 C9105 P9431 P10434 C9153 C9155 P10461 P1450 C9429 C9431 P14519 P14604 C10461 C10515 C11431 C14190 C14488 C14507 C14519 C14556 C14557 C14604 C14626 C14655 C14662 C14670 C14692		5	1	

Injection 50 mg in 0.5 mL single use pre-filled syringe	Injection	Simponi	JC	MP		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 Imatinil	o in the form C	apsule 100 mg (a	s me	silate)						
	(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) <i>omit.</i>	•										
				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 Imatinil	o in the form C	apsule 400 mg (a:	s me	silate)						
	(a) omit.	_	· • . • . • . • . • . • . • . • . •	apoulo ioo iiig (a								
				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	P9204 P9206 P9209 P9240 P9243 P9274 P9276 P9296 P12536 P12541	30	5	30
			C12542 C12543				

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

Infliximab	Powder for I.V. infusion 100 mg	Injection	Inflectra	PF	MP	See Note 3	See Note 3	See Note 3	See Note	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		P14504 P14505 P14585 P14638	3	2	1	PB(100)
			Remicade	JC	MP	C14504 C14505		3	2	1	PB(100)
			Renflexis	OQ	MP		P14504 P14505 P14585 P14638	3	2	1	PB(100)
			Inflectra	PF	MP		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	P13061 P13068	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	P13069 P13077 P13078 P13080	2	2	1
			MP	C11826 C11910 C13039 C13040 C13043 C13045 C13056 C13058 C13061 C13068 C13069 C13077	P13043 P13056 P13079 P14515	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	C13039 C13040	P13040 P13058 P13061 P13068 P13094 P13096	2	0	1
			MP	C13039 C13040	P13078 P13080	2	2	1
			MP		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 omit:	I, Part 1, entry for Insulin r	neutral with i	nsulin 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	
[50]	Schedule 1	I, Part 1, entry for Ixekizun	nab									
Ixekizuma	b	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	P11959 P11981	2	2	2	

MP	C6696 C8830 C8892 C9172 C9429 C9431 C11089 C11096 C11107 C11138 C11154 C11834 C11918 C11958 C11959 C11981	2	3	2
	C14655 C14662 C14670 C14692			

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

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	а	APOHEALTH Macrogol with Electrolytes	GX	MP	See Note 2	See Note 2	See Note 2	See Note 2	1	C(100)
			а	APO-MACROGOL plus ELECTROLYTES	TX	MP	See Note 2	See Note 2	See Note 2	See Note 2	1	C(100)
			а	Chemists' Own Macrogol with Electrolytes	RW	MP	See Note 2	See Note 2	See Note 2	See Note 2	1	C(100)
			а	Macrovic	RF	MP	See Note 2	See Note 2	See Note 2	See Note 2	1	C(100)
			а	Molaxole	GO	MP	See Note 2	See Note 2	See Note 2	See Note 2	1	C(100)

	Marriage	NIE	MD	Can Nata O	Can Nata 2	Can Nata	Cas Nata	4	C(400)
а	Movicol	NE	MP	See Note 2		See Note 2	See Note 2	1	C(100)
	APOHEALTH Macrogol with Electrolytes	GX	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P4576 P4577 P4580 P4596 P4601	1	5	1	
	APO-MACROGOL plus ELECTROLYTES	TX	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P4576 P4577 P4580 P4596 P4601	1	5	1	
	Chemists' Own Macrogol with Electrolytes	RW	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P4576 P4577 P4580 P4596 P4601	1	5	1	
а	Macrovic	RF	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P4576 P4577 P4580 P4596 P4601	1	5	1	
а	Molaxole	GO	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P4576 P4577 P4580 P4596 P4601	1	5	1	
а	Movicol	NE	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P4576 P4577 P4580 P4596 P4601	1	5	1	
	APOHEALTH Macrogol with Electrolytes	GX	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P6171	2	3	1	
	APO-MACROGOL plus ELECTROLYTES	TX	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P6171	2	3	1	
	Chemists' Own Macrogol with Electrolytes	RW	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P6171	2	3	1	
а	Macrovic	RF	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P6171	2	3	1	
а	Molaxole	GO	MP NP	C4576 C4577	P6171	2	3	1	

				C4580 C4596 C4601 C6171				
	a Movi	col NE	MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P6171	2	3	1
52]	Schedule 1, Part 1, entry for Meloxicam in the form Table	7.5 mg						
	insert in the columns in the order indicated, and in alphabetical ord	er for the column	headed "Br	and":				
	Melo	xicam Viatris AL	MP NP	C4907 C4962		30	3	30
53]	Schedule 1, Part 1, entry for Metformin in the form Tablet	containing met	formin hyd	drochloride 50	00 mg			
	insert in the columns in the order indicated, and in alphabetical ord	er for the column	headed "Br	and":				
		nist Metformin	MP NP			100	5	100
64]	Schedule 1, Part 1, entry for Metformin in the form Tablet insert in the columns in the order indicated, and in alphabetical order.	•	-		60 mg			
	· · · · · · · · · · · · · · · ·	nist Metformin	MP NP			60	5	60
55]	Schedule 1, Part 1, entry for Metformin in the form Tablet	containing met	formin hyd	drochloride 1	g			
,5]		_	-		_			
,o]	insert in the columns in the order indicated, and in alphabetical ord	ler for the column	headed "Br	and":				
, o j	a Bloor	ns The BG	headed "Br	and":		90	5	90
56]	a Bloo Cher	ns The BG nist Metformin mg	MP NP		chloride trihyd			

		(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		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 n in 100 mL bottle, 1 mL (S19A)	Oral L	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 n in 300 mL bottle, 1 mL (S19A)	Oral L	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

	(b) <i>omit:</i>			а	Moxonidine MYL	AF	MP NP	C4944 C14289	P4944	30	5	30	
	(b) <i>0mii</i> .												
				а	Moxonidine MYL	AF	MP NP	C4944 C14289	P14289	60	5	30	
)]	Schedule 1	I, Part 1, entry for Mycopl olic acid	nenolic aci	id in tl	ne form Tablet (enter	ic coated	l) containing m	ycophenolate	sodium	equivale	nt to 360	mg
	substitute:												
		Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid	Oral	а	MYCOTEX	CR	MP			120	5	120	
				а	Myfortic	NV	MP			120	5	120	
				а	MYCOTEX	CR	MP		P4084 P4095 P9692 P9809	240 CN4084 CN4095 CN9692 CN9809	5 CN4084 CN4095 CN9692 CN9809	120	C(100)
				а	Myfortic	NV	MP		P4084 P4095 P9692 P9809	240 CN4084 CN4095 CN9692 CN9809	5 CN4084 CN4095 CN9692 CN9809	120	C(100)
)]	Schedule 1	I, Part 1, entry for Nevirap	ine in the	form	Tablet 200 mg								
-		in the column headed "Sched			_	rapine	e Alphapha	vrm ": a					
	` '	t in the columns in the order in	•			-							

	(a) omit:									
		а	Ikorel	SW	MP NP		1	5	1	
	(b) <i>omit:</i>									
		а	Ikorel	SW	MP NP	P14238	2	5	1	
2]	Schedule 1, Part 1, entry for Nivolumab in eac concentrate for I.V. infusion 100 mg in 10 mL	h of th	ne forms: Injecti	on c	oncentrat	te for I.V. infusion 40 m	g in 4 mL; a	nd Inject	ion	
	(a) omit from the column headed "Circumstances	': C13	888							
	(b) insert in numerical order in the column headed	! "Circi	umstances": C146	76						
33]	Schedule 1, Part 1, entry for Octreotide in the	form I	njection 500 mid	rog	rams (as	acetate) in 1 mL				
	omit:									
		а	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 (ora	ally c	lisintegra	ting)				
-	insert in the columns in the order indicated, and in al	habeti	cal order for the co	lumn	headed "E	Brand":				
			Zypine ODT	AF	MP NP	C5856 C5869	28	5	28	
261	Schedule 1, Part 1, entry for Olanzapine in ea Tablet 20 mg (orally disintegrating)	ch of t	he forms: Table	: 10 ı	mg (orally	disintegrating); Table	t 15 mg (ora	lly disint	egrating);	and
65]	insert in the columns in the order indicated, and in al	habeti	cal order for the co	lumn	headed "I	Brand":				
ออา			Zypine ODT	AF	MP NP	C5856 C5869	28	5	28	
							1 14/- 5 00			
66]	Schedule 1, Part 1, entry for Olanzapine in ea	ch of t	he forms: Wafer	5 m	g; Wafer	10 mg; Wafer 15 mg; ar	na water 20	mg		
	Schedule 1, Part 1, entry for Olanzapine in ea	ch of t	he forms: Wafer	5 m	g; Wafer	10 mg; Wafer 15 mg; ar	nd water 20	mg		

67]	Repeats: 5	l, Part 1, entry for Olmesa []	intan in the	101111	Tablet Contain	illing olli	iie Sai tai	i illedoxollili Z	ing [maxii	num Qua	naty. 30	, Number of
	insert in the	columns in the order indicate	d, and in alph	habetio	cal order for the	column h	headed "E	Brand":				
				а	Blooms The Chemist Olmesartan	BG	MP NP			30	5	30
68]	Schedule 1 Repeats: 5	I, Part 1, entry for Olmesa	ertan in the	form	Tablet contain	ning olm	nesartan	n medoxomil 20) mg <i>[Maxii</i>	num Qua	ntity: 60	; Number of
	insert in the	columns in the order indicated	d, and in alph	habeti	cal order for the	column h	headed "E	Brand":				
				а	Blooms The Chemist Olmesartan	BG	MP NP		P14238	60	5	30
200	Cabadula	Dout 4 autus fau Olusaas	wton in the	£	Tablet contain	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	nocartan	modovomil 4	ma Mari	num Ous	ntity: 30	· Number of
ัดลไ	Repeats: 5	 Part 1, entry for Olmesa columns in the order indicated 							ing įmaxii	num Q ua	nary. 50	, Number of
	Repeats: 5					column h			o mg [maxii	30	5	30
	Repeats: 5	columns in the order indicated	d, and in alph	abetic a	Blooms The Chemist Olmesartan	column h	headed "I MP NP	Brand":		30	5	30
[69]	Repeats: 5 insert in the Schedule 1 Repeats: 5	columns in the order indicated	d, and in alph	a form	Blooms The Chemist Olmesartan	BG	headed " <u>I</u> MP NP nesartar	Brand":		30	5	30
	Repeats: 5 insert in the Schedule 1 Repeats: 5	columns in the order indicated 1, Part 1, entry for Olmesa	d, and in alph	a form	Blooms The Chemist Olmesartan	column h	headed " <u>I</u> MP NP nesartar	Brand":		30	5	30
	Repeats: 5 insert in the Schedule 1 Repeats: 5 insert in the	columns in the order indicated 1, Part 1, entry for Olmesa	d, and in alph	a form habetic	Blooms The Chemist Colmesartan Tablet contain Cal order for the Blooms The Chemist Colmesartan	column h	headed "E MP NP nesartan	Brand":) mg <i>[Maxii</i>	30 mum Qua	5 ntity: 60	30 ; Number of
[70]	Repeats: 5 insert in the Schedule 1 Repeats: 5 insert in the	columns in the order indicated to columns in the order indicated in the order indicated in the order indicated columns in the order indicated in the order indic	d, and in alph	a form habetic	Blooms The Chemist Colmesartan Tablet contain Cal order for the Blooms The Chemist Colmesartan	column h	headed "E MP NP nesartan	Brand":) mg <i>[Maxii</i>	30 mum Qua	5 ntity: 60	30 ; Number of

		а	Olmesartan/Amlodi pine 20/5 APOTEX	TX	MP NP	C4373 C14257	P4373	30	5	30
		а	Olmesartan/Amlodi pine - MYL 20/5	AF	MP NP	C4373 C14257	P4373	30	5	30
		а	Olmesartan/Amlodi pine Sandoz	SZ	MP NP	C4373 C14257	P4373	30	5	30
		а	Pharmacor Olmesartan Amlodipine 20/5	CR	MP NP	C4373 C14257	P4373	30	5	30
		а	Sevikar 20/5	AL	MP NP	C4373 C14257	P4373	30	5	30
		а	OLMEKAR	RW	MP NP	C4373 C14257	P14257	60	5	30
		а	Olmesartan/Amlodi pine 20/5 APOTEX	TX	MP NP	C4373 C14257	P14257	60	5	30
		а	Olmesartan/Amlodi pine - MYL 20/5	AF	MP NP	C4373 C14257	P14257	60	5	30
		а	Olmesartan/Amlodi pine Sandoz	SZ	MP NP	C4373 C14257	P14257	60	5	30
		а	Pharmacor Olmesartan Amlodipine 20/5	CR	MP NP	C4373 C14257	P14257	60	5	30
		а	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	а	OLMEKAR	RW	MP NP	C4373		30	5	30
		а	Olmesartan/Amlodi pine 40/5 APOTEX	TX	MP NP	C4373		30	5	30
		а	Olmesartan/Amlodi pine - MYL 40/5	AF	MP NP	C4373		30	5	30
		а	Olmesartan/Amlodi pine Sandoz	SZ	MP NP	C4373		30	5	30

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

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

Zofran Zydis

Oral

omit:

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

AS MP NP

C10498

10

1

10

- [74] Schedule 1, Part 1, omit entry for Pancrelipase
- [75] Schedule 1, Part 1, entry for Pembrolizumab

Wafer 8 mg

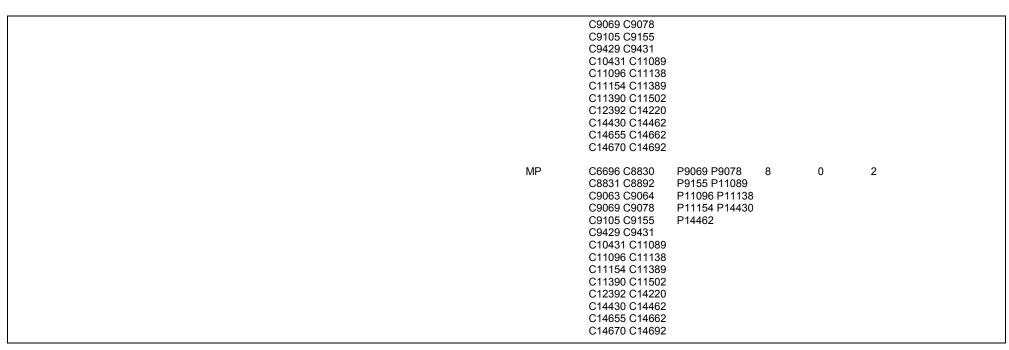
insert in numerical order in the column headed "Circumstances": C14727

	500 mg (as disodium)										
	omit:										
			Pemetrexed-AFT	AE	MP	•		See Note 3	See Note	1	D(100)
7]	Schedule 1, Part 1, entry for Pirfenidone in the for	rm T	ablet 267 mg								
	(a) insert in the columns in the order indicated, and in a	alph	abetical order for	the	colu	mn hea	aded "Brand":				
	e	а	Pirfenidone Ameda	XT	MP)	C13378 C13380 C13381	270	5	90	
	(b) insert in the column headed "Schedule Equivalent"	"for	the brand "Pirfen	idon	e Sa	ndoz":	: a				
'8]	Schedule 1, Part 1, entry for Pirfenidone in the for	rm T	ablet 801mg								
	(a) insert in the columns in the order indicated, and in	alph	abetical order for	the	colu	mn hed	aded "Brand":				
	ε	а	Pirfenidone Ameda	XT	MP	•	C13380	90	5	90	
	(b) insert in the column headed "Schedule Equivalent"	" for	the brand "Pirfen	idon	e Sa	ndoz":	· a				
79]	Schedule 1, Part 1, entry for Pregabalin in each of	f the	forms: Capsul	e 25	5 mg	ј; Сар	sule 75 mg; Capsule 1	I50 mg; and Ca	psule 30) mg	
	insert in the columns in the order indicated, and in alphabe	betica	l order for the co	lumn	hea	ded "E	Brand":				
	- -	а	BTC Pregabalin	BG	MP	NP	C4172	56	5	56	
B0]	Schedule 1, Part 1, entry for Pyridostigmine										
	omit:										
	Tablet containing pyridostigmine Oral bromide 180 mg (modified release) s19A		Pyridostigmine Bromide Extended- Release Tablets (Rising)	DZ	MP	,		100	5	30	
	Schedule 1, Part 1, entry for Raltegravir										
31]											

		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 Ranitidir	10									
		Syrup 150 mg (as hydrochloride) per 10 mL, 300 mL	Oral	Zantac Syrup	AS	MP NP			2	5	1	
33]	Schedule 1 substitute:	, Part 1, entry for Riocigua	at									
iociguat		Tablet 500 micrograms	Oral	Adempas	BN	MP	See Note 3	See Note 3	See Note	See Note	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]		, Part 1, entry for Rosuvas nd Tablet 40 mg (as calciu						10 mg (as cald	cium); Ta	ıblet 20 n	ng (as	
	omit from the	column headed "Authorised I	Prescriber" for	r the brand "Blooms	Rosuva	astatin": I	MP NP NP	substitute: MF	NP			
85]	Schedule 1	, Part 1, entry for Secukin	umab									
	substitute:											
Secukinur	nab	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	P9064 P9429	1	2	1
	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				
MP	C6696 C8830	P9063 P9105	1	5	1
IVII	C8831 C8892	P9431 P10431	ı	5	ı
	C9063 C9064	P14692			
	C9069 C9078	1 14032			
	C9105 C9155				
	C9429 C9431				
	C10431 C11089				
	C11096 C11138				
	C11154 C11389				
	C11390 C11502				
	C12392 C14220				
	C14430 C14462				
	C14655 C14662				
	C14670 C14692				
MP	C6696 C8830	P8831 P9064	2	2	2
	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				
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		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		4	0	1
MP	C6696 C8830 C8831 C8892 C9063 C9064	P11389 P11502 P14220	5	0	1



[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

Tablet (modified release) containing 50 mg sitagliptin with 1000 mg metformin hydrochloride	Oral a	а	Janumet XR X	XW N		C6333 C6334 C6344 C6443 C7507 C7530	56	5	56
				١		C6333 C6334 C6344 C6443 C7530	56	5	56
	6	а	Sitagliptin/Metformi S n Sandoz XR	SZ N	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 w 1000 mg metformin hydrochloride	Oral th	а	Janumet XR	XW	MP	C6333 C6334 C6344 C6443 C7507 C7530	28	5	28
					NP	C6333 C6334 C6344 C6443 C7530	28	5	28
		а	Sitagliptin/Metformi n 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	0 10 1 5	
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- [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

ofacitinib	Oral solution 1 mg per mL, 240 mL	Oral	Xeljanz	PF	MP	C9417 C14647 C14649 C14650 C14652 C14697		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 C14650 C14652 C14655 C14662 C14697 C14720	P11956 P11975 P11976 P12174 P14483 P14486 P14488 P14498 P14649 P14650 P14652 P14655	56	3	56
					MP	C9064 C9417 C9431 C11883 C11886 C11915 C11940 C11944 C11945 C11956 C11975 C11976 C11978 C12174 C12976 C14483 C14486 C14488 C14499 C14507 C14647 C14649 C14650 C14652 C14655 C14662 C14670 C14692	P14499 P14507 P14647 P14692	56	5	56

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

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

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 C14698 C14696 C14698	P13959	28	1	28
					MP	C9064 C9431 C10434 C11886 C11944 C11945 C11956 C11978	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 C14698 C14709	P12499 P12508	28	4	28
MP	C11944 C11945 C11956 C11978 C12174 C12493 C12494 C12499 C12504 C12508	P12493 P12494 P13930 P13958 P14011 P14198 P14199 P14613 P14633 P14692 P14696 P14698	28	5	28

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

						C14728					
	Tablet 45 mg	Oral	Rinvoq	VE	MP	C11976 C13990 C13999 C14014 C14653 C14696 C14710 C14721 C14734	P14710 P14721	28	2	28	
					MP		P11976 P13990 P13999 P14014	28	3	28	
[93]	Schedule 1, Part 1, entry for Vanc	omycin in the	form Powder for i	njectio	n 500 mg	j (500,000 I.U.) (as hydrochlor	ide)			
	substitute:										
	Powder for injection 500 mg (500,000 I.U.) (as hydrochlo		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 Vanc	omycin in the t	form Powder for in	njectio		C5769			0	1	
 [94]	Schedule 1, Part 1, entry for Vanc	comycin in the f	form Powder for i	njectio		C5769			0	1	
[94]		comycin in the f	form Powder for in Vancomycin Alphapharm	njectio AF		C5769			0	1	
[94]	substitute: Powder for injection 1 g (1,000,000 I.U.) (as		Vancomycin		n 1 g (1,0	C5769 000,000 I.U.) (as	hydrochloride	e)			
[94]	substitute: Powder for injection 1 g (1,000,000 I.U.) (as		Vancomycin		n 1 g (1,0	C5769 000,000 I.U.) (as C5716 C5717 C5769	hydrochloride	1	0	1	
[94]	substitute: Powder for injection 1 g (1,000,000 I.U.) (as	Injection	Vancomycin Alphapharm	AF	n 1 g (1,0 MP PDP	C5769 000,000 I.U.) (as C5716 C5717 C5769 C5801 C5716 C5717	hydrochloride P5717	1	0	1	

			C5692 C5725 C5748		
(b) <i>omit:</i>					
	a Vfend	PF MP NP	C4683 C4685 P4683 P5692 C5692 C5725 P5725 P5748 C5748	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	ОС	MP	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328 C14729 C14735	P14729 P14735	1	0	1	PB(100)
			а	APO-Zoledronic Acid	TX	MP	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11	1	PB(100)
			а	DEZTRON	DZ	MP	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11	1	PB(100)
			а	Zoledronate-DRLA 4	RZ	MP	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11	1	PB(100)
			а	Zoledronic Acid Accord	ОС	MP	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328 C14729 C14735	P5605 P5703 P5704 P5735 P9268 P9304 P9317 P9328	1	11	1	PB(100)
			а	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:

mser i.										
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 Oral electrolytes, 500 mL	Movicol Liquid	NE MP NP	C4576 C4577 C4580 C4596 C4601 C6171	P6171	2	3	1		
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					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:

11.1	ALL Pharma Pty Ltd	04 122 146 212
IU	AU Pharma Pty Ltd	84 132 146 313

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

(a) omit:

C11634 P		Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND	Compliance with Authority Required procedures - Streamlined Authority Code 11634
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		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) <i>omit:</i>	<u> </u>		
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 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) a ESR measurement no gre	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:			
C1:	2175 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
C1:	2176 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 dru	Compliance with Writter 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) <i>omit</i> :		
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 sacrolilitis or Grade III unilateral sacrolilitis; 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 hest expansion relative to normal values for age angender; 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 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 be a calcinical munologist; OR 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 prescription form; and (3) a completed authority prescription form; and (4) a completed authority prescription form; and (5) a patient falls to demonstrate a response to an initial course of treatment must be cond	

(f)	omit:			
	C13682	P13682	Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacrolliitis or Grade III unilateral sacrolliitis; 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 stiffiness 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 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 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	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.	
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	C14655	P14655	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	procedures
			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.	
C146	656 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 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 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 contin	Compliance with Written Authority Required procedures
C146	662 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	Compliance with Written
		Initial treatment - Initial 1 (new patient)	Authority Required
		The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral	procedures
		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:

- (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	Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)	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	Authority Required procedures
		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 blogical 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 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first applicat	
		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	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	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	Compliance with Authority Required procedures - Streamlined Authority Code 14701

C14713		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 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 patients' 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. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug if t	Compliance with Written Authority Required procedures
C14730	P14730	Continuing treatment - balance of supply	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 Medic benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	re
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[103] Schedule 4, Part 1, entry for Bimekizumab

	C14438	P14438	Severe chronic plaque psoriasis	Compliance with Written
	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 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 5 weeks; (iii) 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) acitrein 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 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%	
I		1 1	An application for the continuing treatment must be accompanied with the assessment of response conducted following a	1

		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 num	nerical order a	ifter 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 Seventy 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) actiretin 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; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must be at least 18 years of age. Must be treated by a dematologist. 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 value for this treatment cycle. The authority application must be made in writing and must include: (a) a completed Severe Chronic Plaque Psoriasis PBS Authority	,

[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 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 10 mg per L; 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 after a minimum of 5 years have elapsed between the date the	Compliance with Written Authority Required procedures
(b) om	it:			
	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 Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacrolliitis or Grade III unilateral sacrolliitis; 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	
C9537	P9537		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 applications. 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 after a minimum of 5 years have elapsed between the date the last prescrip	
C9610	P9610	Initial treatment - Initial 1 (new patient)	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		Compliance with Written
			Authority Required
		The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND	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 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 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 prescription form; and (3) a completed authority prescription form; and (4) a completed authority prescription form; and (5) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that	
С	14686	P14686	resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)	Compliance with Written Authority Required procedures

		The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroillitis; (ii) Grade III unilateral sacroillitis; 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 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 application form; and (2) a completed authority application form; and (3) 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 repo	
C146	692 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 25 mm per hour; 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 of rithis condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as	
C14714 P14714	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 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 PBSsubsidised 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 PBSsubsidised 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		Compliance with Authority Required procedures
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[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
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	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	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-	mpliance with hority Required cedures - eamlined Authority de 14708
	and cisplatin for dosing information); AND Patient must not have developed disease progression while being treated with this drug for this condition.	

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

(a) *omit*:

C9410	P9410	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.	Compliance with Written Authority Required procedures
		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.	
	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) <i>omit</i>	t:	l l		
	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.	
С	C9487	P9487	Continuing treatment - balance of supply	Compliance with Authority Required procedures
С	29502	P9502	First continuing treatment	Compliance with Written Authority Required procedures

				T
			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 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	Compliance with Written Authority Required procedures
(c) omi	t:			
	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)	Authority Required
			Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND	procedures
			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.	
(d) omit	.	<u>1</u>		1
` ,	C12E4C	D12540	Apladosing approbabilities	Compliance with William
	C13540	F 13540	Ankylosing spondylitis Initial treatment - Initial 1 (new patient)	Compliance with Writt Authority Required
			The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis;	procedures
			AND	procedures
			Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND	
			I due in material have received a bo-substituted treatment with a biological medicine for this condition, AND	1

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.

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 prescription form; and (2) a completed authority prescription form; and any 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 PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application for the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline diseases 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 B	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 have demonstrated an adequate response to treatment with this drug; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must have demonstrated an adequate response to treatment of ankylosing spondylitis. The authority application must be made in writing and must include: (1) 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 2 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 documented in the patient's medical records. An application for the continuing treatment must be documented in the patient's medical records. An application for the continuing treatment must be documented in the patient's medical recor	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 application form; and (2) a completed authority application 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 sacroilitis or Grade III unilateral sacrollitis; and (ii) a baseline BASDAI score; and (iii) a baseline BASDAI score; and (iii) a baseline BSR 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	
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 NSAID strialled, 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 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 a	
C14	4671 F	P14671	Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)	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 sacroililitis; (ii) Grade III unilateral sacroililitis; 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 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 be at least 18 years of age. Must be treated by a relimination of the radiologist; 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 rad	
	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.	
P14673	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	Compliance with Authority Required procedures
	P14673	medicine for this condition, AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacrolilitis; (ii) Grade III unilateral sacrolilitis; 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 rheumatologist: OR Must be treated by a rheumatologist 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 sacrolilitis and (ii) a baseline BASDAI score; and (iii) a baseline BASDAI score; and (iii) a baseline BASDAI score; and (iii) a baseli

		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 10 mg per L; 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	
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.	
C14	4701 F	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	Compliance with Authority Required procedures - Streamlined Authority Code 14701
C14	4703 F	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 have demonstrated an adequate response to treatment with this drug; AND 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 it is not conducted within this treatment cycle. Serious adverse reaction of a severity re	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 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	
C94	9428 F	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 sacroillitis or Grade III unilateral sacroillitis; 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 PBSsubsidised 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 Ankylosina spondylitis Compliance with Written Continuing treatment Authority Required Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this 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 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.	
(c) om	it:			
	C9503	P9503	Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroillitis or Grade III unilateral sacroillitis; 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	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 sacroillitis or Grade III unilateral sacroillitis; 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		Compliance with Written Authority Required procedures	
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		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	Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)	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	Initial treatment - Initial 1 (new patient)	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.	
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	C14692	P14692		Compliance with Written
				Authority Required
			Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this	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.	
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			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.	
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[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:	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). 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.	
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(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	First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority Code 14689
C14701	P14701	Subsequent continuing treatment	Compliance with Authority Required procedures -

			Streamlined Authority Code 14701
C14723 F	P14723	Initial 3 treatment restriction. 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	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.	
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[114] Schedule 4, Part 1, entry for Ixekizumab

(a)	omit:			
	C1099	97 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 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. 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 10 mg per L; or (b) a CRP measurement no greater than 10	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	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 sacroillitis or Grade III unilateral sacroillitis; 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 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 Ankylosing Spondylitis PBS Authority Application Form which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroilitis or Grade III unilateral sacroilitis; 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 re	
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 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 PBSsubsidised 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. insert in numerical order after existing text: (b) C14655 P14655 Ankylosina spondylitis Compliance with Written Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Authority Required Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment procedures

Patient must not receive more than 16 weeks of treatment under this restriction.

cycle: AND

the current treatment cycle: AND

Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during

		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 for a patient form 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 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	
C14662	P14662	Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)	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 c-inical 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 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 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 BA	
C14670	P14670	Ankylosing spondylitis	Compliance with Written Authority Required procedures

014600	D14602	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 13 years of age. Must be treated by a rheumatologist; OR Must be treated by a rheumatologist; OR Must be treated by a rheumatologist 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 application form relevant to the indication and treatment phase (the latest version	
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 PBSsubsidised 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 PBSsubsidised 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:

Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the
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			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 nu	merical 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 Authori Code 14676
16]	Schedule 4, Par	t 1, entry fo	r Pancreatic extract	
		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.	
17]	·		r Pembrolizumab	
	insert in numerica	i oraer ajier e	Stage II or Stage III triple negative breast cancer	Compliance with

				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 omit:	4, Part	1, entry fo	or Pravastatin	
			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 omit:	4, Part	1, entry fo	or Rosuvastatin	
			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	•	1, entry fo	or Secukinumab	
		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.	Compliance with Writte 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 P9	Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)	Compliance with Written Authority Required procedures

(b) omit:		(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.	
	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 of triatment is	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 sacroillitis or Grade III unilateral sacroillitis; 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 feekion 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 clinical immunologist; 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 re	r

	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	C14655	P14655	Ankylosing spondylitis	Compliance with Writte
			Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)	Authority Required
			Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND	procedures
			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.	
C14	4662 P14	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 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 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 have 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 application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following a mism of 12 weeks of	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 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 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 neather and severity of this	

		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 have demonstrated an adequate response to treatment with this drug; AND 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 documented in the patient's medical records. An application for the continuing treatment must be documented in the patient's medical records. An application for the continuing treatment must be documented in the patient's medical records. An application for the continuing treatment must be documented in the patient's medical records. An application for the continuing treatment must be documented in the patient's medical records. An application for the continuing treatment must be documented in the patient's medical	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 omit:	4, Part	t 1, entry fo	or Simvastatin	
			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 omit:	4, Part	t 1, entry fo	or Sulfasalazine	
			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]		-		or Tofacitinib cumstances Code "C9064":	
		C9417	P9417	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	Compliance with Authority Required procedures
				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.	
	(b) omi	t:			

			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.	
		1	Circumstances Code "C11978":	T
	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) omi	t:			
	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 unde	
C1	14211 F	Continuing treatment	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. (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at l	

		(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	Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)	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.	
C1434	5 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 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 details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID is contraindicated according to the relevant period of use which is of a severity to necessitate permanent treatment with NSAIDs is contraindicated according to the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the applicati	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 PBSsubsidised 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	Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements	Compliance with Authority Required procedures
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		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 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,	
C14649	P14649		Compliance with Authority Required procedures

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			(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 charge 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 20 times they will not be el	
C14	4650 P14		Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)	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 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 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 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 tre	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 prescription form; elevant 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 indicato	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	Initial treatment - Ínitial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)	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 sacroilitis; (ii) Grade III unilateral sacroilitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not 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 contraindicated according to the relevant period of use which is of a severity to necessitate permanent treatment with NSAIDs is contraindicated according to the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and sever	

		(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	Continuing treatment	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 (swellen 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 af	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

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:*

C1209	00 P12090	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.	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)	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 sacrolliitis or Grade III unilateral sacrolliitis; 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	Compliance with Written
			Authority Required
		Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this	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 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 the the continuing treatment must be accompanied with the assessment of response following a minimum of	
		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	
		principal response assessment is not conducted within these timenames, the patient will be decined to have falled 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.	
(c) in	sert after e	entry for Circu	umstances 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 clinical immunologist with expertise in the management of ankylosing spondylitis.	Compliance with Authority Required procedures
(d) on	nit:			
	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 W Authority Required

Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment procedures Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. 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 PBSsubsidised 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 PBSsubsidised 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) 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 indica	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 genet; 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 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 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 have 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 prescription form; and (2) a completed authority prescription form; and (3) a baseline BASDAI score; and (4) a baseline ESR and/or CRP level.	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 gener; 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 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 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 Road Patient of the internation of the according to the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide deta	

		(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 have demonstrated an adequate response to treatment with this drug; AND Patient must have demonstrated an adequate response to treatment with this drug; AND 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 prescription 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 10 mg per L; 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 receive further PBS-subsidised tre	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 1 mg per kg daily for 3 or more consecutive months; AND 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 intestina. Must be treated by a consultant physician [general medic	Compliance with Writter 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	8 P14698	Balance of supply for the Continuing (maintenance) treatment phase	Compliance with Authority Required procedures
C14709	9 P14709	Continuing (maintenance) treatment	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 P1471	Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)	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 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 as specified below; OR Patient must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below. The authority application must be	Compliance with Written Authority Required procedures

	in the a Evider (i) bloc hour, c (ii) facilities mesen All ass should most rulf treat Product If intole treatm Details Any or continue be use	tient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient. Indeed,	
C14728 P1	Contin Must be Must be Must be Patien conditi Patien a level Patien demor than 2 lactofe compatotal patien The coapplica Patien The au (1) a c (2) a c websit	nuing (maintenance) treatment	Compliance with Written Authority Required procedures

	(ii) the unique serial/identifying	ast administered dose: Index (CDAI) score, including the date the score was calculated on; or g number and date(s) of pathology or diagnostic imaging test(s) used to assess response to gut syndrome, extensive small intestine disease or an ostomy, if relevant.	
C14734 P14	Initial treatment - Initial 2 (cha Must be treated by a gastroer Must be treated by a consulta Must be treated by a consulta Patient must have received procycle; AND The treatment must not have current treatment cycle. Patient must be at least 18 ye The authority application mus (1) a completed authority pres (2) a completed authority apply website specified in the Admin In relation to the biological memore than 4 weeks from the lation to the biological memore than 4 weeks from the lation to the process of the control of the	Inge or recommencement of treatment after a break in biological medicine of less than 5 years) interologist (code 87); OR interplay internal medicine specialising in gastroenterology (code 81)]; OR interplay internal medicine specialising in gastroenterology (code 82)]. For PBS-subsidised treatment with a biological medicine for this condition in this treatment on a previous occasion failed to provide the patient with an adequate response during the stars of age. In the made in writing and must include: scription form; and dication form relevant to the indication and treatment phase (the latest version is located on the instrative Advice). In the scription of the following which is not service in the scription of the following which is not service in the scription of the following which is not service in the scription of the following which is not service in the scription of the following which is not service in the scription of the following which is not service in the scription of the following which is not service in the scription of the following which is not service in the scription of the following which is not service in the scription of the following which is not service in the scription of the following which is not service in the scription of the scription of the following which is not service in the scription of the	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:

С	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
С	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)		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

omit:

GR	RP-25645	Capsule 100 mg (as mesilate)	IMATINIB-DRLA Imatinib-APOTEX
		Tablet 100 mg (as mesilate)	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:

Gl	SRP-25647	Capsule 400 mg (as mesilate)	Imatinib-APOTEX IMATINIB-DRLA Imatinib GH
		Tablet 400 mg (as mesilate)	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:

	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)		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)		Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL)

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

	Wafer 8 mg	Oral	Zofran Zydis
			Ondansetron SZ ODT Zotren ODT

[147] Schedule 5, omit entry for Pancrelipase

[148] Schedule 5, omit entry for Pyridostigmine