PB 54 of 2023

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 6)

National Health Act 1953

I, SOUMYA SUDARSHAN, Assistant Secretary (Acting), 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 29 June 2023

SOUMYA SUDARSHAN
Assistant Secretary (Acting)
Pricing and PBS Policy Branch
Technology Assessment and Access Division

Contents

1 Name

(1) This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 6)*.

(2) This Instrument may also be cited as PB 54 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 July 2023*	*1 July 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Abatacept in the form Injection 125 mg in 1 mL single dose autoinjector *[Maximum Quantity: 4; Number of Repeats: 3]***

(a) *omit from the column headed "Circumstances":* **C8746**

(b) *insert in numerical order in the column headed "Circumstances":* **C14142**

(c) *omit from the column headed "Purposes":* **P8746**

(d) *insert in numerical order in the column headed "Purposes":* **P14142**

[2] **Schedule 1, Part 1, entry for Abatacept in the form Injection 125 mg in 1 mL single dose autoinjector *[Maximum Quantity: 4; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C8746**

(b) *insert in numerical order in the column headed "Circumstances":* **C14142**

[3] **Schedule 1, Part 1, entry for Abatacept in the form Injection 125 mg in 1 mL single dose pre-filled syringe *[Maximum Quantity: 4; Number of Repeats: 3]***

(a) *omit from the column headed "Circumstances":* **C8746**

(b) *insert in numerical order in the column headed "Circumstances":* **C14142**

(c) *omit from the column headed "Purposes":* **P8746**

(d) *insert in numerical order in the column headed "Purposes":* **P14142**

[4] **Schedule 1, Part 1, entry for Abatacept in the form Injection 125 mg in 1 mL single dose pre-filled syringe *[Maximum Quantity: 4; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C8746**

(b) *insert in numerical order in the column headed "Circumstances":* **C14142**

[5] **Schedule 1, Part 1, after entry for Acalabrutinib in the form Capsule 100 mg**

insert:

Tablet 100 mg	Oral	CALQUENCE	AP	MP	C10652 C12481 C12495 C12500	56	5	56

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

substitute:

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

					MP	C9715 C11579 C11713 C11715 C11716 C11717 C11718 C11761 C11767 C11852 C11853 C11854 C11855 C11903 C11966	P9715 P11715 P11716 P11761 P11852 P11854 P11855	2	3	1	
					MP	C9715 C11579 C11713 C11715 C11716 C11717 C11718 C11761 C11767 C11852 C11853 C11854 C11855 C11903 C11966	P11579 P11717 P11718 P11767 P11853 P11903 P11966	2	5	1	
					MP	C14107 C14136		2	5	1	C(100)
	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Humira	VE	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
			Yuflyma	EW	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
			Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155	P11713	2	0	2	

				C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Yuflyma	EW	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175	P11713	2	0	2

				C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2

				C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Yuflyma	EW	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2

				C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P8638 P9064 P9386 P11861 P12131 P12174 P12194 P13550 P13599 P13606 P13648 P13650 P13681 P13682 P13694 P14058	2	3	2
	Yuflyma	EW	MP	C8638 C9064 C9386 C9715	P8638 P9064 P9386 P11861	2	3	2

				C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P12131 P12174 P12194 P13550 P13599 P13606 P13648 P13650 P13681 P13682 P13694 P14058			
	Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711	P11107 P12155 P12212 P13556 P13607 P13612 P13683	2	4	2

			C11713 C11715 C11716 C11717 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Yuflyma	EW	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720	P11107 P12155 P12212 P13556 P13607 P13612 P13683	2	4	2

				C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966	P11704 P11711 P11717 P11720 P11767 P11769 P11772 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12175 P12176 P12189 P12190 P12214 P12228 P12234 P12240	2	5	2	

				C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
			MP	C14107 C14136		2	5	2	C(100)
	Yuflyma	EW	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098	P11523 P11524 P11579 P11604 P11605 P11606 P11631 P11634 P11635 P11704 P11711 P11717 P11718 P11720 P11767 P11769 P11772 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12175 P12176 P12189 P12190 P12214 P12228 P12234 P12240	2	5	2	

				C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
			MP	C14107 C14136		2	5	2	C(100)
	Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174	P12273	4	2	2	

				C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Yuflyma	EW	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194	P12273	4	2	2

				C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606	P12272 P12315	4	5	2

			C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058					
	Yuflyma	EW	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650	P11529 P12272 P12315	4	5	2

				C13681 C13682 C13683 C13694 C14058				
	Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336 P13602 P13609	6	0	2
	Yuflyma	EW	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854	6	0	2

					C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P11855 P12098 P12101 P12147 P12275 P12336 P13602 P13609				
Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Humira	VE	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
		Yuflyma	EW	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)

	Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P11713	2	0	2
	Yuflyma	EW	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716	P11713	2	0	2

				C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2	

				C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Yuflyma	EW	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2	

				C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650	P8638 P9064 P9386 P11861 P12131 P12174 P12194 P13550 P13599 P13606 P13648 P13650 P13681 P13682 P13694 P14058	2	3	2	

				C13681 C13682 C13683 C13694 C14058				
	Yuflyma	EW	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P8638 P9064 P9386 P11861 P12131 P12174 P12194 P13550 P13599 P13606 P13648 P13650 P13681 P13682 P13694 P14058	2	3	2
	Humira	VE	MP	C8638 C9064	P11107 P12155	2	4	2

			C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P12212 P13556 P13607 P13612 P13683			
	Yuflyma	EW	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718	P11107 P12155 P12212 P13556 P13607 P13612 P13683	2	4	2

				C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123	P11704 P11711 P11717 P11720 P11767 P11769 P11772 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12175 P12176 P12189 P12190 P12214 P12228 P12234 P12240	2	5	2	

				C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
			MP	C14107 C14136		2	5	2	C(100)
	Yuflyma	EW	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157	P11523 P11524 P11579 P11604 P11605 P11606 P11631 P11634 P11635 P11704 P11711 P11717 P11718 P11720 P11767 P11769 P11772 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12175 P12176 P12189 P12190 P12214 P12228 P12234 P12240	2	5	2	

				C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
			MP	C14107 C14136		2	5	2	C(100)
	Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	6	0	2	

			C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
Yuflyma	EW	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	6	0	2

					C14058					
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	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234	P11713	2	0	2	

				C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Hadlima	RF	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275	P11713	2	0	2

				C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556	P11713	2	0	2

				C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Idacio	PK	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607	P11713	2	0	2

				C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Amgevita	XT	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2

				C13681 C13682 C13683 C13694 C14058				
	Hadlima	RF	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2

				C14058				
	Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2

	Idacio	PK	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2
	Amgevita	XT	MP	C8638 C9064 C9386 C9715	P8638 P9064 P9386 P11861	2	3	2

				C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P12131 P12174 P12194 P13550 P13599 P13606 P13648 P13650 P13681 P13682 P13694 P14058			
	Hadlima	RF	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529	P8638 P9064 P9386 P11861 P12131 P12174 P12194 P13550	2	3	2

				C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P13599 P13606 P13648 P13650 P13681 P13682 P13694 P14058			
	Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606	P8638 P9064 P9386 P11861 P12131 P12174 P12194 P13550 P13599 P13606 P13648 P13650	2	3	2

				C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P13681 P13682 P13694 P14058			
	Idacio	PK	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704	P8638 P9064 P9386 P11861 P12131 P12174 P12194 P13550 P13599 P13606 P13648 P13650 P13681 P13682 P13694 P14058	2	3	2

				C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Amgevita	XT	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715	P11107 P12155 P12212 P13556 P13607 P13612 P13683	2	4	2

				C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Hadlima	RF	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720	P11107 P12155 P12212 P13556 P13607 P13612 P13683	2	4	2

				C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769	P11107 P12155 P12212 P13556 P13607 P13612 P13683	2	4	2

				C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Idacio	PK	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854	P11107 P12155 P12212 P13556 P13607 P13612 P13683	2	4	2

				C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Amgevita	XT	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867	P11523 P11524 P11579 P11604 P11605 P11606 P11631 P11634 P11635 P11704 P11711 P11717 P11718 P11720 P11767 P11769 P11772 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12175 P12176 P12189 P12190 P12214 P12228 P12234	2	5	2	

				C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P12240			
			MP	C14107 C14136		2	5	2	C(100)
Hadlima		RF	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867	P11523 P11524 P11579 P11604 P11605 P11606 P11631 P11634 P11635 P11704 P11711 P11717 P11718 P11720 P11767 P11769 P11772 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12175 P12176 P12189 P12190 P12214 P12228 P12234	2	5	2	

				C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P12240			
			MP	C14107 C14136		2	5	2	C(100)
	Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867	P11523 P11524 P11579 P11604 P11605 P11606 P11631 P11634 P11635 P11704 P11711 P11717 P11718 P11720 P11767 P11769 P11772 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12175 P12176 P12189 P12190 P12214 P12228 P12234	2	5	2	

				C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P12240			
			MP	C14107 C14136		2	5	2	C(100)
	Idacio	PK	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867	P11523 P11524 P11579 P11604 P11605 P11606 P11631 P11634 P11635 P11704 P11711 P11717 P11718 P11720 P11767 P11769 P11772 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12175 P12176 P12189 P12190 P12214 P12228 P12234	2	5	2	

				C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P12240			
			MP	C14107 C14136		2	5	2	C(100)
	Amgevita	XT	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867	P12273	4	2	2	

				C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Hadlima	RF	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098	P12273	4	2	2

				C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131	P12273	4	2	2

				C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Idacio	PK	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156	P12273	4	2	2

				C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Amgevita	XT	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175	P11529 P12272 P12315	4	5	2

				C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Hadlima	RF	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194	P11529 P12272 P12315	4	5	2

				C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234	P11529 P12272 P12315	4	5	2

				C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Idacio	PK	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275	P11529 P12272 P12315	4	5	2

				C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Amgevita	XT	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336 P13602 P13609	6	0	2

				C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Hadlima	RF	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336 P13602 P13609	6	0	2

				C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336 P13602 P13609	6	0	2

				C13681 C13682 C13683 C13694 C14058				
	Idacio	PK	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336 P13602 P13609	6	0	2

					C14058					
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	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240	P11713	2	0	2	

				C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Hadlima	RF	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650	P11713	2	0	2

				C13681 C13682 C13683 C13694 C14058				
	Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P11713	2	0	2
	Idacio	PK	MP	C8638 C9064	P11713	2	0	2

				C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058					
	Amgevita	XT	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147	2	2	2	

				C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P13602 P13609			
	Hadlima	RF	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2

				C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2	

				C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Idacio	PK	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2	

				C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Amgevita	XT	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176	P8638 P9064 P9386 P11861 P12131 P12174 P12194 P13550 P13599 P13606 P13648 P13650 P13681 P13682 P13694 P14058	2	3	2	

				C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Hadlima	RF	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556	P8638 P9064 P9386 P11861 P12131 P12174 P12194 P13550 P13599 P13606 P13648 P13650 P13681 P13682 P13694 P14058	2	3	2

				C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682	P8638 P9064 P9386 P11861 P12131 P12174 P12194 P13550 P13599 P13606 P13648 P13650 P13681 P13682 P13694 P14058	2	3	2

				C13683 C13694 C14058				
	Idacio	PK	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P8638 P9064 P9386 P11861 P12131 P12174 P12194 P13550 P13599 P13606 P13648 P13650 P13681 P13682 P13694 P14058	2	3	2
	Amgevita	XT	MP	C8638 C9064 C9386 C9715	P11107 P12155 P12212 P13556	2	4	2

				C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P13607 P13612 P13683			
	Hadlima	RF	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635	P11107 P12155 P12212 P13556 P13607 P13612 P13683	2	4	2

				C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759	P11107 P12155 P12212 P13556 P13607 P13612 P13683	2	4	2

				C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Idacio	PK	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865	P11107 P12155 P12212 P13556 P13607 P13612 P13683	2	4	2

				C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Amgevita	XT	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147	P11523 P11524 P11579 P11604 P11605 P11606 P11631 P11634 P11635 P11704 P11711 P11717 P11718 P11720 P11767 P11769 P11772 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12175 P12176 P12189 P12190 P12214 P12228 P12234 P12240	2	5	2

				C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
			MP	C14107 C14136		2	5	2	C(100)
	Hadlima	RF	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174	P11523 P11524 P11579 P11604 P11605 P11606 P11631 P11634 P11635 P11704 P11711 P11717 P11718 P11720 P11767 P11769 P11772 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12175 P12176 P12189 P12190 P12214 P12228 P12234 P12240	2	5	2	

				C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
			MP	C14107 C14136		2	5	2	C(100)
	Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212	P11523 P11524 P11579 P11604 P11605 P11606 P11631 P11634 P11635 P11704 P11711 P11717 P11718 P11720 P11767 P11769 P11772 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12175 P12176 P12189 P12190 P12214 P12228 P12234 P12240	2	5	2	

				C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058					
			MP	C14107 C14136		2	5	2	C(100)
	Idacio	PK	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556	P11523 P11524 P11579 P11604 P11605 P11606 P11631 P11634 P11635 P11704 P11711 P11717 P11718 P11720 P11767 P11769 P11772 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12175 P12176 P12189 P12190 P12214 P12228 P12234 P12240	2	5	2	

				C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
			MP	C14107 C14136		2	5	2	C(100)
	Amgevita	XT	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	6	0	2	

				C13648 C13650 C13681 C13682 C13683 C13694 C14058				
	Hadlima	RF	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	6	0	2

	Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	6	0	2
	Idacio	PK	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098	6	0	2

					C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P12101 P12147 P13602 P13609			
Injection 80 mg in 0.8 mL pre-filled pen	Injection	Humira	VE	MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12153 C12155 C12161 C12212 C12229 C12273 C12275 C12278	P12103 P12105 P12153 P12155 P12161 P12212	1	0	1

					C12306				
				MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12153 C12155 C12161 C12212 C12229 C12273 C12275 C12278 C12306	P12273	2	2	1
				MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12153 C12155 C12161 C12212 C12229 C12273 C12275 C12278 C12306	P12306	2	5	1
				MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12153 C12155 C12161 C12212 C12229 C12273 C12275 C12278 C12306	P11715 P11716 P11759 P11761 P11762 P11763 P11852 P11854 P11855 P12152 P12229 P12275 P12278	3	0	1
Injection 80 mg in 0.8 mL pre-filled syringe	Injection	Humira	VE	MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152	P12103 P12105 P12153 P12155 P12161 P12212	1	0	1

	C12153 C12155 C12161 C12212 C12229 C12273 C12275 C12278 C12306				
MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12153 C12155 C12161 C12212 C12229 C12273 C12275 C12278 C12306	P12273	2	2	1
MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12153 C12155 C12161 C12212 C12229 C12273 C12275 C12278 C12306	P12306	2	5	1
MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12153 C12155 C12161 C12212 C12229 C12273 C12275 C12278 C12306	P11715 P11716 P11759 P11761 P11762 P11763 P11852 P11854 P11855 P12152 P12229 P12275 P12278	3	0	1

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

omit:

	a	Alendronate plus D3-DRLA	RZ	MP NP	C6307 C6315 C6320	4	5	4	

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

omit:

	a	Alendronate plus D3-DRLA	RZ	MP NP	C6306 C6319 C6325	4	5	4	

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

insert:

Avatrombopag	Tablet 20 mg	Oral	Doptelet	ZO	MP	See Note 3	See Note 3	See Note 3	See Note 3	30	D(100)

[10] **Schedule 1, Part 1, entry for Azacitidine**

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

	a	Azacitidine Sandoz	SZ	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

[11] **Schedule 1, Part 1, entry for Azathioprine in the form Tablet 25 mg**

omit:

	a	Azathioprine GH	GQ	MP NP		100	5	100	

[12] **Schedule 1, Part 1, entry for Baricitinib in the form Tablet 2 mg *[Maximum Quantity: 28; Number of Repeats: 3]***

(a) *omit from the column headed "Circumstances":* **C8750**

(b) *insert in numerical order in the column headed "Circumstances":* **C14184**

(c) *omit from the column headed "Purposes":* **P8750**

(d) *insert in numerical order in the column headed "Purposes":* **P14184**

[13] **Schedule 1, Part 1, entry for Baricitinib in the form Tablet 2 mg *[Maximum Quantity: 28; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C8750**

(b) *insert in numerical order in the column headed "Circumstances":* **C14184**

[14] **Schedule 1, Part 1, entry for Baricitinib in the form Tablet 4 mg *[Maximum Quantity: 28; Number of Repeats: 3]***

(a) *omit from the column headed "Circumstances":* **C8750**

(b) *insert in numerical order in the column headed "Circumstances":* **C14184**

(c) *omit from the column headed "Purposes":* **P8750**

(d) *insert in numerical order in the column headed "Purposes":* **P14184**

[15] **Schedule 1, Part 1, entry for Baricitinib in the form Tablet 4 mg *[Maximum Quantity: 28; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C8750**

(b) *insert in numerical order in the column headed "Circumstances":* **C14184**

[16] **Schedule 1, Part 1, entry for Budesonide with formoterol in the form Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses**

substitute:

Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	a	BiResp Spiromax	TB	MP	C7970 C10464 C10538	P10464	1	2	1
					NP	C7970 C10464	P10464	1	2	1
		a	DuoResp Spiromax	EV	MP	C7970 C10464 C10538	P10464	1	2	1
					NP	C7970 C10464	P10464	1	2	1
		a	Rilast TURBUHALER 200/6	ZA	MP	C7970 C10464 C10538	P10464	1	2	1
					NP	C7970 C10464	P10464	1	2	1

	a	Symbicort Turbuhaler 200/6	AP	MP	C7970 C10464 C10538	P10464	1	2	1
				NP	C7970 C10464	P10464	1	2	1
	a	BiResp Spiromax	TB	MP	C7970 C10464 C10538	P7970 P10538	1	5	1
				NP	C7970 C10464	P7970	1	5	1
	a	DuoResp Spiromax	EV	MP	C7970 C10464 C10538	P7970 P10538	1	5	1
				NP	C7970 C10464	P7970	1	5	1
	a	Rilast TURBUHALER 200/6	ZA	MP	C7970 C10464 C10538	P7970 P10538	1	5	1
				NP	C7970 C10464	P7970	1	5	1
	a	Symbicort Turbuhaler 200/6	AP	MP	C7970 C10464 C10538	P7970 P10538	1	5	1
				NP	C7970 C10464	P7970	1	5	1

[17] Schedule 1, Part 1, entry for Budesonide with formoterol in the form Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses

substitute:

Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses	Inhalation by mouth	a	Rilast TURBUHALER 400/12	ZA	MP NP	C7979 C10121		2	5	1
		a	Symbicort TURBUHALER 400/12	AP	MP NP	C7979 C10121		2	5	1
		a	BiResp Spiromax	TB	MP NP	C7979 C10121		2	5	2

			a	DuoResp Spiromax	EV	MP NP	C7979 C10121	2	5	2

[18] Schedule 1, Part 1, omit entry for Budesonide with formoterol in the form Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses, 2

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

substitute:

Buprenorphine	Injection (modified release) 8 mg in 0.16 mL pre-filled syringe	Injection	Buvidal Weekly	UR	MP NP	C14075	4	2	1	PB(100)
	Injection (modified release) 16 mg in 0.32 mL pre-filled syringe	Injection	Buvidal Weekly	UR	MP NP	C14075	4	2	1	PB(100)
	Injection (modified release) 24 mg in 0.48 mL pre-filled syringe	Injection	Buvidal Weekly	UR	MP NP	C14075	4	2	1	PB(100)
	Injection (modified release) 32 mg in 0.64 mL pre-filled syringe	Injection	Buvidal Weekly	UR	MP NP	C14075	4	2	1	PB(100)
	Injection (modified release) 64 mg in 0.18 mL pre-filled syringe	Injection	Buvidal Monthly	UR	MP NP	C14139	1	2	1	PB(100)
	Injection (modified release) 96 mg in 0.27 mL pre-filled syringe	Injection	Buvidal Monthly	UR	MP NP	C14139	1	2	1	PB(100)
	Injection (modified release) 100 mg in 0.5 mL pre-filled syringe	Injection	Sublocade	IR	MP NP	C14138	1	2	1	PB(100)
	Injection (modified release) 128 mg in 0.36 mL pre-filled syringe	Injection	Buvidal Monthly	UR	MP NP	C14139	1	2	1	PB(100)
	Injection (modified release) 160 mg in 0.45 mL pre-filled syringe	Injection	Buvidal Monthly	UR	MP NP	C14139	1	2	1	PB(100)

Injection (modified release) 300 mg in 1.5 mL pre-filled syringe	Injection		Sublocade	IR	MP NP	C14138		1	2	1	PB(100)
Transdermal patch 5 mg	Transdermal	a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
Transdermal patch 10 mg	Transdermal	a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
Transdermal patch 15 mg	Transdermal	a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		a	Buprenorphine	SZ	MP NP	C10748 C10752	P10748 P10752	2	0	2	

			Sandoz			C10755 C11753	P10755			
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
Transdermal patch 20 mg	Transdermal	a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2
Transdermal patch 25 mg	Transdermal	a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2
		a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2

		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
Transdermal patch 30 mg	Transdermal	a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
Transdermal patch 40 mg	Transdermal	a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		a	Bupredermal	TX	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
		a	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
		a	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
Tablet (sublingual) 400 micrograms (as	Sublingual		Subutex	IR	MP NP	C14157		28	2	7	PB(100)

	hydrochloride)									
	Tablet (sublingual) 2 mg (as hydrochloride)	Sublingual	Subutex	IR	MP NP	C14157	84	2	7	PB(100)
	Tablet (sublingual) 8 mg (as hydrochloride)	Sublingual	Subutex	IR	MP NP	C14157	112	2	7	PB(100)

[20] Schedule 1, Part 1, entry for Buprenorphine with naloxone

substitute:

Buprenorphine with naloxone	Film (soluble) 2 mg (as hydrochloride)-0.5 mg (as hydrochloride)	Sublingual	Suboxone Film 2/0.5	IR	MP NP	C14074	84	2	28	D(100)
	Film (soluble) 8 mg (as hydrochloride)-2 mg (as hydrochloride)	Sublingual	Suboxone Film 8/2	IR	MP NP	C14074	112	2	28	D(100)

[21] Schedule 1, Part 1, entry for Candesartan in each of the forms: Tablet containing candesartan cilexetil 4 mg; Tablet containing candesartan cilexetil 8 mg; Tablet containing candesartan cilexetil 16 mg; and Tablet containing candesartan cilexetil 32 mg

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

		a	BTC Candesartan	BG	MP NP		30	5	30

[22] Schedule 1, Part 1, entry for Certolizumab pegol in the form Injection 200 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 0]*

(a) *omit from the column headed "Circumstances":* **C8626**

(b) *insert in numerical order in the column headed "Circumstances":* **C14113**

[23] Schedule 1, Part 1, entry for Certolizumab pegol in the form Injection 200 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 2]*

(a) *omit from the column headed "Circumstances":* **C8626**

(b) *insert in numerical order in the column headed "Circumstances":* **C14113**

[24] **Schedule 1, Part 1, entry for Certolizumab pegol in the form Injection 200 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C8626**

(b) *insert in numerical order in the column headed "Circumstances":* **C14113**

[25] **Schedule 1, Part 1, entry for Certolizumab pegol in the form Injection 200 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 6; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances":* **C8626**

(b) *insert in numerical order in the column headed "Circumstances":* **C14113**

(c) *omit from the column headed "Purposes":* **P8626**

(d) *insert in numerical order in the column headed "Purposes":* **P14113**

[26] **Schedule 1, Part 1, entry for Certolizumab pegol in the form Solution for injection 200 mg in 1 mL pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances":* **C8626**

(b) *insert in numerical order in the column headed "Circumstances":* **C14113**

[27] **Schedule 1, Part 1, entry for Certolizumab pegol in the form Solution for injection 200 mg in 1 mL pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* **C8626**

(b) *insert in numerical order in the column headed "Circumstances":* **C14113**

[28] **Schedule 1, Part 1, entry for Certolizumab pegol in the form Solution for injection 200 mg in 1 mL pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C8626**

(b) *insert in numerical order in the column headed "Circumstances":* **C14113**

[29] **Schedule 1, Part 1, entry for Certolizumab pegol in the form Solution for injection 200 mg in 1 mL pre-filled pen *[Maximum Quantity: 6; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances":* **C8626**

(b) *insert in numerical order in the column headed "Circumstances":* **C14113**

(c) *omit from the column headed "Purposes":* **P8626**

(d) *insert in numerical order in the column headed "Purposes":* **P14113**

[30] Schedule 1, Part 1, entry for Choriogonadotropin alfa

substitute:

Choriogonadotropin alfa	Solution for injection 250 micrograms in 0.5 mL pre-filled pen	Injection	Ovidrel	SG	MP	C14124		1	0	1	C(100)
					MP	C14096		1	5	1	

[31] Schedule 1, Part 1, entry for Escitalopram in each of the forms: Tablet 10 mg (as oxalate); and Tablet 20 mg (as oxalate)

omit from the column headed "Circumstances" for the brand "APO-Escitalopram": **C4755** *substitute:* **C4690 C4703 C4755 C4756 C4757**

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

(a) *omit:*

			Esomeprazole Sandoz	SZ	MP	C8774 C8775 C8776 C8780 C8827 C11310	P8774 P8775	30	1	30	
					NP	C8774 C8775 C8776 C8780 C8827	P8774 P8775	30	1	30	

(b) *omit:*

			Esomeprazole SZ	HX	MP	C8774 C8775 C8776 C8780 C8827 C11310	P8774 P8775	30	1	30	
					NP	C8774 C8775 C8776 C8780 C8827	P8774 P8775	30	1	30	

(c) *omit:*

			Esomeprazole Sandoz	SZ	MP	C8774 C8775 C8776 C8780 C8827 C11310	P8776 P8780 P8827	30	5	30	

			NP	C8774 C8775 C8776 C8780 C8827	P8776 P8780 P8827	30	5	30

(d) *omit:*

Esomeprazole SZ	HX	MP	C8774 C8775 C8776 C8780 C8827 C11310	P8776 P8780 P8827	30	5	30
		NP	C8774 C8775 C8776 C8780 C8827	P8776 P8780 P8827	30	5	30

(e) *omit:*

Esomeprazole Sandoz	SZ	MP	C8774 C8775 C8776 C8780 C8827 C11310	P11310	60	5	30

(f) *omit:*

Esomeprazole SZ	HX	MP	C8774 C8775 C8776 C8780 C8827 C11310	P11310	60	5	30

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

(a) *omit:*

Esomeprazole Sandoz	SZ	MP	C8777 C8778 C8902 C11370	P8902	30	1	30
		NP	C8777 C8778 C8902	P8902	30	1	30

(b) *omit:*

Esomeprazole SZ	HX	MP	C8777 C8778 C8902 C11370	P8902	30	1	30
		NP	C8777 C8778 C8902	P8902	30	1	30

(c) *omit:*

			Esomeprazole Sandoz	SZ	MP	C8777 C8778 C8902 C11370	P8777 P8778	30	5	30
					NP	C8777 C8778 C8902	P8777 P8778	30	5	30

(d) *omit:*

			Esomeprazole SZ	HX	MP	C8777 C8778 C8902 C11370	P8777 P8778	30	5	30
					NP	C8777 C8778 C8902	P8777 P8778	30	5	30

(e) *omit:*

			Esomeprazole Sandoz	SZ	MP	C8777 C8778 C8902 C11370	P11370	60	5	30

(f) *omit:*

			Esomeprazole SZ	HX	MP	C8777 C8778 C8902 C11370	P11370	60	5	30

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

substitute:

Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection	Enbrel	PF	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	C(100)
					MP	C14154 C14155		1	5	1	C(100)
					MP	C7289 C8638 C8662 C8692 C8718 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380	P8638 P9064 P9386 P9388 P9410 P9429 P9473 P11107 P12164 P12260 P12261 P12262 P12265 P12266 P12287 P12289	2	3	1	

	C9386 C9388 C9410 C9429 C9473 C9487 C9502 C9554 C11107 C12164 C12260 C12261 C12262 C12265 C12266 C12287 C12289 C12327 C12434 C12457 C13532 C13533 C13535 C13537 C13538 C13539 C13540 C13542 C13593 C13598 C13646 C13647 C13707 C14108	P12327 P12434 P12457 P13532 P13533 P13535 P13537 P13538 P13539 P13540 P13542 P13593 P13598 P13646 P13647 P13707 P14108			
MP	C7289 C8638 C8662 C8692 C8718 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9410 C9429 C9473 C9487 C9502 C9554 C11107 C12164 C12260 C12261 C12262 C12265 C12266 C12287 C12289 C12327 C12434 C12457 C13532 C13533 C13535 C13537 C13538 C13539 C13540 C13542 C13593 C13598 C13646 C13647 C13707 C14108	P7289 P8662 P8692 P8718 P8839 P8842 P8873 P8879 P9081 P9123 P9140 P9162 P9377 P9380 P9487 P9502 P9554	2	5	1

	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)
			Brenzys	RF	MP	C7276 C7289 C8638 C8662 C8692 C8718 C8839 C8842 C8873 C8879 C8887 C8955 C9064 C9081 C9123 C9140 C9156 C9162 C9410 C9429 C9481 C9487 C9502 C9554 C11107 C13532 C13533 C13535 C13537 C13538 C13539 C13540 C13542 C13593 C13598 C13646 C13647 C13707 C14108	P8638 P9064 P9410 P9429 P11107 P13532 P13533 P13535 P13537 P13538 P13539 P13540 P13542 P13593 P13598 P13646 P13647 P13707 P14108	1	3	1	
			Enbrel	PF	MP	C7289 C8638 C8662 C8692 C8718 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9410 C9429 C9473 C9487 C9502 C9554 C11107 C12164 C12260 C12261 C12262 C12265 C12266 C12287 C12289 C12327 C12434 C12457 C13532 C13533 C13535 C13537	P8638 P9064 P9386 P9388 P9410 P9429 P9473 P11107 P12164 P12260 P12261 P12262 P12265 P12266 P12287 P12289 P12327 P12434 P12457 P13532 P13533 P13535 P13537 P13538 P13539 P13540 P13542 P13593 P13598 P13646 P13647 P13707 P14108	1	3	1	

				C13538 C13539 C13540 C13542 C13593 C13598 C13646 C13647 C13707 C14108				
	Brenzys	RF	MP	C7276 C7289 C8638 C8662 C8692 C8718 C8839 C8842 C8873 C8879 C8887 C8955 C9064 C9081 C9123 C9140 C9156 C9162 C9410 C9429 C9481 C9487 C9502 C9554 C11107 C13532 C13533 C13535 C13537 C13538 C13539 C13540 C13542 C13593 C13598 C13646 C13647 C13707 C14108	P7276 P7289 P8662 P8692 P8718 P8839 P8842 P8873 P8879 P8887 P8955 P9081 P9123 P9140 P9156 P9162 P9481 P9487 P9502 P9554	1	5	1
	Enbrel	PF	MP	C7289 C8638 C8662 C8692 C8718 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9410 C9429 C9473 C9487 C9502 C9554 C11107 C12164 C12260 C12261 C12262 C12265 C12266 C12287 C12289 C12327	P7289 P8662 P8692 P8718 P8839 P8842 P8873 P8879 P9081 P9123 P9140 P9162 P9377 P9380 P9487 P9502 P9554	1	5	1

					C12434 C12457 C13532 C13533 C13535 C13537 C13538 C13539 C13540 C13542 C13593 C13598 C13646 C13647 C13707 C14108					
				MP	C14154 C14155		1	5	1	C(100)
Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Enbrel	PF	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	C(100)
		Brenzys	RF	MP	C7276 C7289 C8638 C8662 C8692 C8718 C8839 C8842 C8873 C8879 C8887 C8955 C9064 C9081 C9123 C9140 C9156 C9162 C9410 C9429 C9481 C9487 C9502 C9554 C11107 C13532 C13533 C13535 C13537 C13538 C13539 C13540 C13542 C13593 C13598 C13646 C13647 C13707 C14108	P8638 P9064 P9410 P9429 P11107 P13532 P13533 P13535 P13537 P13538 P13539 P13540 P13542 P13593 P13598 P13646 P13647 P13707 P14108	1	3	1	
		Enbrel	PF	MP	C7289 C8638 C8662 C8692 C8718 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388	P8638 P9064 P9386 P9388 P9410 P9429 P9473 P11107 P12164 P12260 P12261 P12262 P12265 P12266 P12287 P12289 P12327 P12434	1	3	1	

				C9410 C9429 C9473 C9487 C9502 C9554 C11107 C12164 C12260 C12261 C12262 C12265 C12266 C12287 C12289 C12327 C12434 C12457 C13532 C13533 C13535 C13537 C13538 C13539 C13540 C13542 C13593 C13598 C13646 C13647 C13707 C14108	P12457 P13532 P13533 P13535 P13537 P13538 P13539 P13540 P13542 P13593 P13598 P13646 P13647 P13707 P14108			
	Brenzys	RF	MP	C7276 C7289 C8638 C8662 C8692 C8718 C8839 C8842 C8873 C8879 C8887 C8955 C9064 C9081 C9123 C9140 C9156 C9162 C9410 C9429 C9481 C9487 C9502 C9554 C11107 C13532 C13533 C13535 C13537 C13538 C13539 C13540 C13542 C13593 C13598 C13646 C13647 C13707 C14108	P7276 P7289 P8662 P8692 P8718 P8839 P8842 P8873 P8879 P8887 P8955 P9081 P9123 P9140 P9156 P9162 P9481 P9487 P9502 P9554	1	5	1
	Enbrel	PF	MP	C7289 C8638 C8662 C8692 C8718 C8839 C8842 C8873 C8879 C9064 C9081 C9123	P7289 P8662 P8692 P8718 P8839 P8842 P8873 P8879 P9081 P9123 P9140 P9162	1	5	1

							C9140 C9162 P9377 P9380 C9377 C9380 P9487 P9502 C9386 C9388 P9554 C9410 C9429 C9473 C9487 C9502 C9554 C11107 C12164 C12260 C12261 C12262 C12265 C12266 C12287 C12289 C12327 C12434 C12457 C13532 C13533 C13535 C13537 C13538 C13539 C13540 C13542 C13593 C13598 C13646 C13647 C13707 C14108				
					MP	C14154 C14155		1	5	1	C(100)

[35] Schedule 1, Part 1, entry for Ezetimibe and rosuvastatin in each of the forms: Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 10 mg (as calcium); Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 20 mg (as calcium); and Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 40 mg (as calcium)

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

				a	Pharmacor Ezetimibe Rosuvastatin Composite Pack	CR	MP NP	C7957		1	5	1	

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

insert:

Finerenone	Tablet 10 mg	Oral	Kerendia	BN	MP NP	C14097		28	5	28	
	Tablet 20 mg	Oral	Kerendia	BN	MP NP	C14097		28	5	28	

[37] Schedule 1, Part 1, entry for Fingolimod in the form Capsule 500 micrograms (as hydrochloride)

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

	a	FINGOLIS	LR	MP	C10162 C10172		28	5	28

[38] Schedule 1, Part 1, entry for Fluticasone propionate in the form Pressurised inhalation containing fluticasone propionate 50 micrograms per dose, 120 doses (CFC-free formulation)

omit from the column headed "Circumstances" (all instances): **C13917** *substitute (all instances):* **C14180**

[39] Schedule 1, Part 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 3]*

(a) *omit from the column headed "Circumstances":* **C8741**

(b) *insert in numerical order in the column headed "Circumstances":* **C14171**

(c) *omit from the column headed "Purposes":* **P8741**

(d) *insert in numerical order in the column headed "Purposes":* **P14171**

[40] Schedule 1, Part 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C8741**

(b) *insert in numerical order in the column headed "Circumstances":* **C14171**

[41] Schedule 1, Part 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 3]*

(a) *omit from the column headed "Circumstances":* **C8741**

(b) *insert in numerical order in the column headed "Circumstances":* **C14171**

(c) *omit from the column headed "Purposes":* **P8741**

(d) *insert in numerical order in the column headed "Purposes":* **P14171**

[42] Schedule 1, Part 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C8741**

(b) *insert in numerical order in the column headed "Circumstances":* **C14171**

[43] Schedule 1, Part 1, entry for Irbesartan in each of the forms: Tablet 75 mg; Tablet 150 mg; and Tablet 300 mg

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

			a	Noumed Irbesartan	VO	MP NP			30	5	30	

[44] Schedule 1, Part 1, entry for Lamivudine with zidovudine

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

			a	Lamivudine/Zidovudine Viatris 150/300	AL	MP NP	C4454 C4512		120	5	60	D(100)

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

omit:

			a	Lamotrigine Sandoz	SZ	MP NP	C11081		56	5	56	

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

omit:

			a	Sandoz Metformin	HX	MP NP			90	5	90	

[47] Schedule 1, Part 1, entry for Methadone

substitute:

Methadone	Injection containing methadone hydrochloride 10 mg in 1 mL	Injection		Physeptone	AS	MP NP	C10745 C10747 C10751 C11696	P10745 P10747 P10751	5	0	5	
						MP NP	C10745 C10747 C10751 C11696	P11696	120	0	5	
	Oral liquid containing methadone hydrochloride 25 mg per 5 mL in 1 L bottle, 1 mL	Oral	a	Aspen Methadone Syrup	AS	MP NP	C14178		840	2	1000	PB(100)
			a	Biodone Forte	MW	MP NP	C14178		840	2	1000	PB(100)
	Oral liquid containing methadone hydrochloride 25 mg per 5 mL in 200 mL bottle, 1 mL	Oral		Aspen Methadone Syrup	AS	MP NP	C4902 C4941	P4941	200	0	200	
						MP NP	C4902 C4941	P4902	200	2	200	
			a	Aspen Methadone	AS	MP NP	C14178		840	2	200	C(100)

				Syrup							
			a	Biodone Forte	MW	MP NP	C14178		840	2	200	C(100)
	Tablet containing methadone hydrochloride 10 mg	Oral		Physeptone	AS	MP NP	C10745 C10747 C10751 C11696	P10745 P10747 P10751	20	0	20	
						MP NP	C10745 C10747 C10751 C11696	P11696	120	0	20	

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

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

			a	Blooms The Chemist Mirtazapine	BG	MP NP	C5650		30	5	30	

[49] Schedule 1, Part 1, entry for Mirtazapine in the form Tablet 15 mg (orally disintegrating)

omit:

			a	Mirtazapine Sandoz ODT 15	SZ	MP NP	C5650		30	5	30	

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

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

			a	Blooms The Chemist Mirtazapine	BG	MP NP	C5650		30	5	30	

[51] Schedule 1, Part 1, entry for Mirtazapine in the form Tablet 30 mg (orally disintegrating)

omit:

			a	Mirtazapine Sandoz ODT 30	SZ	MP NP	C5650		30	5	30	

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

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

	a	Blooms The Chemist Mirtazapine	BG	MP NP	C5650		30	5	30

[53] Schedule 1, Part 1, entry for Mirtazapine in the form Tablet 45 mg (orally disintegrating)

omit:

	a	Mirtazapine Sandoz ODT 45	SZ	MP NP	C5650		30	5	30

[54] Schedule 1, Part 1, entry for Nirmatrelvir and ritonavir

(a) *omit from the column headed "Circumstances":* **C13765**

(b) *omit from the column headed "Circumstances":* **C13893**

(c) *insert in numerical order in the column headed "Circumstances":* **C14187**

[55] Schedule 1, Part 1, entry for Oxycodone in the form Capsule containing oxycodone hydrochloride 10 mg

substitute:

Capsule containing oxycodone hydrochloride 10 mg	Oral	OxyNorm	MF	MP NP	C10764 C10766 C10771 C10772	P10766	10	0	20
				PDP	C10766 C10768	P10766	10	0	20
				MP NP	C10764 C10766 C10771 C10772	P10764 P10771 P10772	20	0	20
				PDP	C10766 C10768	P10768	20	0	20

[56] Schedule 1, Part 1, entry for Paroxetine

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

	a	Noumed Paroxetine	VO	MP NP	C4755 C6277 C6636		30	5	30

[57] Schedule 1, Part 1, after entry for Pemetrexed in the form Powder for I.V. infusion 1 g (as disodium)

insert:

	Solution concentrate for I.V. infusion 100 mg (as disodium) in 4 mL	Injection	Pemetrexed Ever Pharma	IT	MP			See Note 3	See Note 3	1	D(100)
	Solution concentrate for I.V. infusion 500 mg (as disodium) in 20mL	Injection	Pemetrexed Ever Pharma	IT	MP			See Note 3	See Note 3	1	D(100)
	Solution concentrate for I.V. infusion 1 g (as disodium) in 40 mL	Injection	Pemetrexed Ever Pharma	IT	MP			See Note 3	See Note 3	1	D(100)

[58] Schedule 1, Part 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 80 mg

(a) *omit:*

	a	Pravastatin Sandoz	SZ	MP NP			30	5	30	

(b) *omit:*

	a	Pravastatin Sandoz	SZ	MP		P7598	30	11	30	

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

omit:

		Rizatriptan-AU	DZ	MP NP	C5708		4	5	2	

[60] Schedule 1, Part 1, entry for Telmisartan in the form Tablet 40 mg

omit:

	a	Telmisartan GH	GQ	MP NP			28	5	28	

[61] Schedule 1, Part 1, entry for Tocilizumab

substitute:

Tocilizumab	Concentrate for injection 80 mg in 4 mL	Injection	Actemra	RO	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)
					MP	C14082 C14093 C14164 C14179	P14082 P14164	2	5	1	PB(100)

				MP	C14082 C14093 C14164 C14179	P14093 P14179	4	5	1	PB(100)
Concentrate for injection 200 mg in 10 mL	Injection	Actemra	RO	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)
				MP	C14082 C14093 C14164 C14179	P14082 P14164	1	5	1	PB(100)
				MP	C14082 C14093 C14164 C14179	P14093 P14179	2	5	1	PB(100)
Concentrate for injection 400 mg in 20 mL	Injection	Actemra	RO	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)
				MP	C14082 C14093 C14164 C14179	P14082 P14164	1	5	1	PB(100)
				MP	C14082 C14093 C14164 C14179	P14093 P14179	2	5	1	PB(100)
Injection 162 mg in 0.9 mL single use pre-filled pen	Injection	Actemra ACTPen	RO	MP	C8627 C8633 C8638 C9180 C9380 C9386 C9391 C9477 C9478 C9553 C10560 C11689 C11781 C12193 C12399 C12404 C12405 C14056 C14080 C14084 C14088 C14094 C14103 C14104 C14121 C14147 C14150 C14153 C14166 C14174 C14175 C14182	P10560	4	0	4	
				MP	C8627 C8633 C8638 C9180 C9380 C9386 C9391 C9477 C9478 C9553 C10560 C11689	P9477 P12404 P14094 P14103 P14121 P14153 P14166 P14182	4	1	4	

	C11781 C12193 C12399 C12404 C12405 C14056 C14080 C14084 C14088 C14094 C14103 C14104 C14121 C14147 C14150 C14153 C14166 C14174 C14175 C14182				
MP	C8627 C8633 C8638 C9180 C9380 C9386 C9391 C9477 C9478 C9553 C10560 C11689 C11781 C12193 C12399 C12404 C12405 C14056 C14080 C14084 C14088 C14094 C14103 C14104 C14121 C14147 C14150 C14153 C14166 C14174 C14175 C14182	P14084 P14104 P14150	4	2	4
MP	C8627 C8633 C8638 C9180 C9380 C9386 C9391 C9477 C9478 C9553 C10560 C11689 C11781 C12193 C12399 C12404 C12405 C14056 C14080 C14084 C14088 C14094 C14103 C14104 C14121 C14147 C14150 C14153 C14166 C14174 C14175 C14182	P8638 P9386 P9391 P9478 P11689 P11781 P12193 P12399 P12405 P14056 P14080 P14147 P14175	4	3	4

				MP	C8627 C8633 C8638 C9180 C9380 C9386 C9391 C9477 C9478 C9553 C10560 C11689 C11781 C12193 C12399 C12404 C12405 C14056 C14080 C14084 C14088 C14094 C14103 C14104 C14121 C14147 C14150 C14153 C14166 C14174 C14175 C14182	P8627 P8633 P9380 P9553 P14088 P14174	4	5	4
				MP	C8627 C8633 C8638 C9180 C9380 C9386 C9391 C9477 C9478 C9553 C10560 C11689 C11781 C12193 C12399 C12404 C12405 C14056 C14080 C14084 C14088 C14094 C14103 C14104 C14121 C14147 C14150 C14153 C14166 C14174 C14175 C14182	P9180	4	6	4
Injection 162 mg in 0.9 mL single use pre-filled syringe	Injection	Actemra Subcutaneous Injection	RO	MP	C8627 C8633 C8638 C9180 C9380 C9386 C9391 C9477 C9478 C9553 C10560 C11689 C11781 C12193 C12399 C12404 C12405 C14056 C14080 C14084	P10560	4	0	4

		C14088 C14094 C14103 C14104 C14121 C14147 C14150 C14153 C14166 C14174 C14175 C14182				
	MP	C8627 C8633 C8638 C9180 C9380 C9386 C9391 C9477 C9478 C9553 C10560 C11689 C11781 C12193 C12399 C12404 C12405 C14056 C14080 C14084 C14088 C14094 C14103 C14104 C14121 C14147 C14150 C14153 C14166 C14174 C14175 C14182	P9477 P12404 P14094 P14103 P14121 P14153 P14166 P14182	4	1	4
	MP	C8627 C8633 C8638 C9180 C9380 C9386 C9391 C9477 C9478 C9553 C10560 C11689 C11781 C12193 C12399 C12404 C12405 C14056 C14080 C14084 C14088 C14094 C14103 C14104 C14121 C14147 C14150 C14153 C14166 C14174 C14175 C14182	P14084 P14104 P14150	4	2	4
	MP	C8627 C8633 C8638 C9180 C9380 C9386	P8638 P9386 P9391 P9478 P11689 P11781	4	3	4

	C9391 C9477 C9478 C9553 C10560 C11689 C11781 C12193 C12399 C12404 C12405 C14056 C14080 C14084 C14088 C14094 C14103 C14104 C14121 C14147 C14150 C14153 C14166 C14174 C14175 C14182	P12193 P12399 P12405 P14056 P14080 P14147 P14175			
MP	C8627 C8633 C8638 C9180 C9380 C9386 C9391 C9477 C9478 C9553 C10560 C11689 C11781 C12193 C12399 C12404 C12405 C14056 C14080 C14084 C14088 C14094 C14103 C14104 C14121 C14147 C14150 C14153 C14166 C14174 C14175 C14182	P8627 P8633 P9380 P9553 P14088 P14174	4	5	4
MP	C8627 C8633 C8638 C9180 C9380 C9386 C9391 C9477 C9478 C9553 C10560 C11689 C11781 C12193 C12399 C12404 C12405 C14056 C14080 C14084 C14088 C14094 C14103 C14104 C14121 C14147	P9180	4	6	4

	C14150 C14153 C14166 C14174 C14175 C14182

[62] **Schedule 1, Part 1, entry for Tofacitinib in the form Tablet 5 mg *[Maximum Quantity: 56; Number of Repeats: 3]***

(a) *omit from the column headed "Circumstances":* **C8750**

(b) *insert in numerical order in the column headed "Circumstances":* **C14185**

(c) *omit from the column headed "Purposes":* **P8750**

(d) *insert in numerical order in the column headed "Purposes":* **P14185**

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

(a) *omit from the column headed "Circumstances":* **C8750**

(b) *insert in numerical order in the column headed "Circumstances":* **C14185**

[64] **Schedule 1, Part 1, entry for Upadacitinib in the form Tablet 15 mg *[Maximum Quantity: 28; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* **C10376**

(b) *insert in numerical order in the column headed "Circumstances":* **C14170**

[65] **Schedule 1, Part 1, entry for Upadacitinib in the form Tablet 15 mg *[Maximum Quantity: 28; Number of Repeats: 3]***

(a) *omit from the column headed "Circumstances":* **C10376**

(b) *insert in numerical order in the column headed "Circumstances":* **C14170**

(c) *omit from the column headed "Purposes":* **P10376**

(d) *insert in numerical order in the column headed "Purposes":* **P14170**

[66] **Schedule 1, Part 1, entry for Upadacitinib in the form Tablet 15 mg *[Maximum Quantity: 28; Number of Repeats: 4]***

(a) *omit from the column headed "Circumstances":* **C10376**

(b) *insert in numerical order in the column headed "Circumstances":* **C14170**

[67] **Schedule 1, Part 1, entry for Upadacitinib in the form Tablet 15 mg *[Maximum Quantity: 28; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C10376**

(b) *insert in numerical order in the column headed "Circumstances":* **C14170**

[68] Schedule 1, Part 1, entry for Zanubrutinib

omit from the column headed "Circumstances": **C13020**

[69] Schedule 1, Part 2, omit entry for Budesonide with formoterol

[70] Schedule 1, Part 2, omit entry for Ertugliflozin with metformin

[71] Schedule 1, Part 2, omit entry for Nicotine

[72] Schedule 4, Part 1, entry for Abatacept

(a) *omit:*

	C8746	P8746		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months). Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an	Compliance with Written Authority Required procedures

				application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats. Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

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

	C14142	P14142		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months). Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:	Compliance with Written Authority Required procedures

				(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder 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). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats. Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

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

(a) *omit:*

	C11526			Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) 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 rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. 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). If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

(b) *omit:*

	C11810	P11810		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) 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 rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. 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). If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

(c) *omit:*

	C12116			Severe active juvenile idiopathic arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.	Compliance with Authority Required procedures - Streamlined Authority

				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 per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). 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 submitted with the initial treatment application. 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 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	Code 12116

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

	C14058	P14058		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least	Compliance with Written Authority Required procedures

				20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. 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). If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	
	C14107			Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony	Compliance with Authority Required procedures - Streamlined Authority Code 14107

				overgrowth). The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C14136			Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-	Compliance with Authority Required procedures - Streamlined Authority Code 14136

				subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	

[74] Schedule 4, Part 1, entry for Baricitinib

(a) *omit:*

	C8750	P8750		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this 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	Compliance with Written Authority Required procedures

				for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

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

	C14184	P14184		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of	Compliance with Written Authority Required procedures

				treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

[75] Schedule 4, Part 1, entry for Buprenorphine

(a) *omit:*

	C6451			Opiate dependence Maintenance and detoxification (withdrawal) The treatment must be within a framework of medical, social and psychological treatment.	
	C9212			Opiate dependence Must be treated by a health care professional. The treatment must be within a framework of medical, social and psychological treatment; AND Patient must be stabilised on sublingual buprenorphine or buprenorphine/naloxone prior to commencing treatment with this drug for this condition.	

(b) *omit:*

	C12701			Opiate dependence Must be treated by a health care professional. The treatment must be within a framework of medical, social and psychological treatment.	
	C12915			Opiate dependence Must be treated by a health care professional. The treatment must be within a framework of medical, social and psychological treatment; AND Patient must be stabilised on one of the following prior to commencing treatment with this drug for this condition: (i) weekly prolonged release buprenorphine (Buvidal Weekly) (ii) sublingual buprenorphine (iii) buprenorphine/naloxone.	

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

	C14075			Opioid dependence Must be treated by a health care professional. The treatment must be within a framework of medical, social and psychological treatment.	Compliance with Authority Required procedures - Streamlined Authority Code 14075
	C14138			Opioid dependence Must be treated by a health care professional. The treatment must be within a framework of medical, social and psychological treatment; AND Patient must be stabilised on sublingual buprenorphine or buprenorphine/naloxone prior to commencing treatment with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 14138
	C14139			Opioid dependence Must be treated by a health care professional. The treatment must be within a framework of medical, social and psychological treatment; AND Patient must be stabilised on one of the following prior to commencing treatment with this drug for this condition: (i) weekly prolonged release buprenorphine (Buvidal Weekly) (ii) sublingual buprenorphine (iii) buprenorphine/naloxone.	Compliance with Authority Required procedures - Streamlined Authority Code 14139
	C14157			Opioid dependence The treatment must be within a framework of medical, social and psychological treatment. A medical practitioner must request a quantity sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 2 repeats will be authorised. A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.	Compliance with Authority Required procedures - Streamlined Authority Code 14157

[76] Schedule 4, Part 1, entry for Buprenorphine with naloxone

substitute:

Buprenorphine with naloxone	C14074			Opioid dependence The treatment must be within a framework of medical, social and psychological treatment. A medical practitioner must request a quantity sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 2 repeats will be authorised. A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.	Compliance with Authority Required procedures - Streamlined Authority Code 14074

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

(a) *omit:*

	C8626	P8626		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months). 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 rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; 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. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

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

	C14113	P14113		Severe active rheumatoid arthritis	Compliance with Written

				Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months). Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; 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. Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive	Authority Required procedures

				further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

[78] Schedule 4, Part 1, entry for Choriogonadotropin alfa

substitute:

Choriogonadotropin alfa	C14096			Infertility indications other than that of Assisted Reproductive Technology Patient must not be undergoing treatment with medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule; AND Patient must not be undergoing simultaneous treatment with this drug through another PBS program listing; AND Must be treated by an obstetrician/gynaecologist; OR Must be treated by a specialist in reproductive endocrinology/infertility; OR Must be treated by a urogynaecologist; OR Must be treated by an endocrinologist; OR Must be treated by a urologist. The PBS prescription, whether it is to initiate or continue treatment, must be made out under the specialist's prescriber number.	
	C14124			Assisted Reproductive Technology Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule. Patient must not be undergoing simultaneous treatment with this drug through another PBS program listing.	Compliance with Authority Required procedures - Streamlined Authority Code 14124

[79] Schedule 4, Part 1, omit entry for Ertugliflozin with metformin

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

(a) *omit:*

	C8760	P8760		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older.	Compliance with Written Authority Required procedures

				An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

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

	C14108	P14108		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND	Compliance with Written Authority Required procedures

				Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	
	C14154			Severe active juvenile idiopathic arthritis Continuing treatment	Compliance with Authority Required

				Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application. At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	procedures - Streamlined Authority Code 14154
	C14155			Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:	Compliance with Authority Required procedures - Streamlined Authority Code 14155

				(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. At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	

[81] Schedule 4, Part 1, after entry for Filgrastim

insert:

Finerenone	C14097			Chronic kidney disease with Type 2 diabetes Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug; AND Patient must not have known significant non-diabetic renal disease, prior to initiating treatment with this drug; AND Patient must have an estimated glomerular filtration rate of 25 mL/min/1.73 m 2 or greater, prior to initiating treatment with this drug; AND Patient must have a urinary albumin-to-creatinine ratio of 200 mg/g (22.6 mg/mmol) or greater, prior to initiating treatment with this drug; AND Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant; AND Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug; AND The treatment must be in combination with an SGLT2i unless medically contraindicated or intolerant; AND Patient must not be receiving treatment with another selective nonsteroidal mineralocorticoid receptor antagonist, a renin inhibitor or a potassium-sparing diuretic; AND Patient must not have established heart failure with reduced ejection fraction with an indication for treatment with a mineralocorticoid receptor antagonist.	Compliance with Authority Required procedures - Streamlined Authority Code 14097

[82] Schedule 4, Part 1, entry for Fluticasone propionate

substitute:

Fluticasone propionate	C14180			Asthma The treatment must not be a PBS benefit where this 50 microgram strength is being initiated in a patient over the age of 6.00 years.	Compliance with Authority Required procedures - Streamlined Authority Code 14180

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

(a) *omit:*

	C8741	P8741		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the	Compliance with Written Authority Required procedures

				most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

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

	C14171	P14171		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and	Compliance with Written Authority Required procedures

				limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

[84] Schedule 4, Part 1, entry for Methadone

(a) *omit:*

	C6480			Opiate dependence	

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

	C14178			Opioid dependence The treatment must be within a framework of medical, social and psychological treatment. A medical practitioner must request a quantity (in millilitres) sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 2 repeats will be authorised. A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.	Compliance with Authority Required procedures - Streamlined Authority Code 14178

[85] Schedule 4, Part 1, entry for Nirmatrelvir and ritonavir

(a) *omit:*

	C13765			SARS-CoV-2 infection	Compliance with

				Patient must have received a positive polymerase chain reaction (PCR) test result; OR Patient must have received a positive rapid antigen test (RAT) result; AND Patient must have at least one sign or symptom attributable to COVID-19; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND The treatment must be initiated within 5 days of symptom onset. Patient must be both: (i) at least 50 years of age, (ii) at high risk. For the purpose of administering this restriction, high risk is defined as either a past COVID-19 infection episode resulting in hospitalisation, or the presence of at least two of the following conditions: 1. The patient is in residential aged care, 2. The patient has disability with multiple comorbidities and/or frailty, 3. Neurological conditions, including stroke and dementia and demyelinating conditions, 4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease, 5. Heart failure, coronary artery disease, cardiomyopathies, 6. Obesity (BMI greater than 30 kg/m2), 7. Diabetes type I or II, requiring medication for glycaemic control, 8. Renal impairment (eGFR less than 60mL/min), 9. Cirrhosis, or 10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above. Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records. For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell. Access to this drug through this restriction is permitted irrespective of vaccination status. Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record. Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record. This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.	Authority Required procedures - Streamlined Authority Code 13765

(b) *omit:*

	C13893			SARS-CoV-2 infection Patient must have received a positive polymerase chain reaction (PCR) test result; OR Patient must have received a positive rapid antigen test (RAT) result; AND Patient must have at least one sign or symptom attributable to COVID-19; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND The treatment must be initiated within 5 days of symptom onset. Patient must be at least 60 years old, but not older than 70 years; AND Patient must be at high risk of requiring hospitalisation for COVID-19 infection. For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions: 1. The patient is in residential aged care	Compliance with Authority Required procedures - Streamlined Authority Code 13893

				2. The patient has disability with multiple comorbidities and/or frailty 3. Neurological conditions, including stroke and dementia and demyelinating conditions 4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease 5. Heart failure, coronary artery disease, cardiomyopathies 6. Obesity (BMI greater than 30 kg/m2) 7. Diabetes type I or II, requiring medication for glycaemic control 8. Renal impairment (eGFR less than 60mL/min) 9. Cirrhosis 10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above 11. Past COVID-19 infection episode resulting in hospitalisation. Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records. For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell. Access to this drug through this restriction is permitted irrespective of vaccination status. Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record. Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record. This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.	

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

	C14187			SARS-CoV-2 infection Patient must have received a positive polymerase chain reaction (PCR) test result; OR Patient must have received a positive rapid antigen test (RAT) result; AND Patient must have at least one sign or symptom attributable to COVID-19; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND The treatment must be initiated within 5 days of symptom onset. Patient must be at high risk of requiring hospitalisation for COVID-19 infection; AND Patient must be at least 50 years old, but not older than 60 years; OR Patient must be at least 60 years old, but not older than 70 years. For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions: 1. The patient is in residential aged care 2. The patient has disability with multiple comorbidities and/or frailty 3. Neurological conditions, including stroke and dementia and demyelinating conditions 4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease 5. Heart failure, coronary artery disease, cardiomyopathies 6. Obesity (BMI greater than 30 kg/m2) 7. Diabetes type I or II, requiring medication for glycaemic control	Compliance with Authority Required procedures - Streamlined Authority Code 14187

				8. Renal impairment (eGFR less than 60mL/min) 9. Cirrhosis 10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above 11. Past COVID-19 infection episode resulting in hospitalisation. Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records. For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell. Access to this drug through this restriction is permitted irrespective of vaccination status. Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record. Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record. This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.	

[86] Schedule 4, Part 1, entry for Tocilizumab

substitute:

Tocilizumab	C8627	P8627		Severe active rheumatoid arthritis Continuing Treatment - balance of supply. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.	Compliance with Authority Required procedures
	C8633	P8633		Severe active rheumatoid arthritis Continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. 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. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:	Compliance with Written Authority Required procedures

				(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C8638	P8638		Severe active rheumatoid arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. 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 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	Compliance with Authority Required procedures
	C9180	P9180		Active giant cell arteritis Continuing treatment Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed 52 weeks in total including initial and continuing applications.	Compliance with Authority Required procedures
	C9380	P9380		Severe active juvenile idiopathic arthritis	Compliance with

				Continuing Treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.	Authority Required procedures
	C9386	P9386		Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. 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 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	Compliance with Authority Required procedures
	C9391	P9391		Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Active joints are defined as: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count must be no more than 4 weeks old at the time of this application. The authority application must be made in writing and must include:	Compliance with Written Authority Required procedures

				(1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. 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. 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.	
	C9477	P9477		Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 16 or 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 or 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 or 24 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions for patients 30 kg or over; OR The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions for patients under 30 kg.	Compliance with Authority Required procedures
	C9478	P9478		Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND	Compliance with Written Authority Required procedures

				Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) 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 authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis 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. 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 who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C9553	P9553		Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. 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 per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) 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). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 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. 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. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C10560	P10560		Systemic juvenile idiopathic arthritis Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months) - in a patient of any	Compliance with Authority Required procedures

				weight being administered a subcutaneous form of this biological medicine 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 (retrial or recommencement of treatment after a break 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 Initial 3 (recommencement of treatment after a break 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 therapy available under Initial 1, 2 or 3 treatment. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.	
	C11689	P11689		Severe active rheumatoid arthritis Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the	Compliance with Written Authority Required procedures

				most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this 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 under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C11781	P11781		Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of	Compliance with Written Authority Required procedures

				contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this 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 under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C12193	P12193		Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response	Compliance with Written Authority Required procedures

				to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list: (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 joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why	

				this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - 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.	
	C12399	P12399		Severe active juvenile idiopathic arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 16 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: (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). If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) 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	Compliance with Written Authority Required procedures

				pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C12404	P12404		Severe active juvenile idiopathic arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab) 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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab. Patient must be under 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction. If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20	Compliance with Written Authority Required procedures

				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). To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C12405	P12405		Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 16 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: (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). If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate	Compliance with Written Authority Required procedures

				response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14056	P14056		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;	Compliance with Written Authority Required procedures

				AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	
	C14080	P14080		Systemic juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient weighing at least 30 kg) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age. Must be treated by a rheumatologist; OR	Compliance with Authority Required procedures

				Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient 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 of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to prior treatment must be documented in the patient's medical records. The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application: (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN). The assessment of response to prior treatment must be documented in the patient's medical records. The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with other treatments 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 assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The 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 systemic juvenile idiopathic arthritis; and (b) details of prior treatment including dose and duration of treatment. The following reports must be documented in the patient's medical records where appropriate: (a) the date of assessment of severe active systemic juvenile idiopathic arthritis; (b) details of prior treatment including dose and duration of treatment; and (c) the pathology reports detailing CRP and platelet count where appropriate.	
	C14082	P14082		Severe active juvenile idiopathic arthritis Continuing treatment	Compliance with Authority Required

				Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	procedures - Streamlined Authority Code 14082
	C14084	P14084		Systemic juvenile idiopathic arthritis Continuing treatment in a patient weighing less than 30 kg Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. An adequate response to treatment is defined as: (a) in a patient with polyarticular course disease: (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or	Compliance with Authority Required procedures - Streamlined Authority Code 14084

				(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%: - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or - 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). (b) in a patient with refractory systemic symptoms: (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dose of corticosteroid by at least 30% from baseline. 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 measurements of disease severity provided with the initial treatment application. The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records. 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. The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment. If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14088	P14088		Systemic juvenile idiopathic arthritis Continuing treatment in a patient weighing at least 30 kg Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. An adequate response to treatment is defined as: (a) in a patient with polyarticular course disease: (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%: - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or - shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).	Compliance with Authority Required procedures - Streamlined Authority Code 14088

				(b) in a patient with refractory systemic symptoms: (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dose of corticosteroid by at least 30% from baseline. 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 measurements of disease severity provided with the initial treatment application. The following reports must be documented in the patient's medical records where appropriate: (a) baseline and current pathology reports detailing C-reactive protein (CRP) levels; and (b) baseline and current pathology reports detailing platelet count. The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records. 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. The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment. If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14093	P14093		Systemic juvenile idiopathic arthritis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. An adequate response to treatment is defined as: (a) in a patient with polyarticular course disease: (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%: - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or - 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). (b) in a patient with refractory systemic symptoms: (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or	Compliance with Authority Required procedures - Streamlined Authority Code 14093

				(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dose of corticosteroid by at least 30% from baseline. 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 measurements of disease severity provided with the initial treatment application. The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records. At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised. 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. The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment. If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14094	P14094		Systemic juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient weighing less than 30 kg) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient 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 of major joints: (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	Compliance with Authority Required procedures

				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 following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application: (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN). The assessment of response to prior treatment must be documented in the patient's medical records. The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with other treatments 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 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 systemic juvenile idiopathic arthritis; and (b) the details of prior treatment including dose and duration of treatment. The following reports must be documented in the patient's medical records where appropriate: (a) pathology reports detailing C-reactive protein (CRP) level and platelet count. 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.	
	C14103	P14103		Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD),	Compliance with Authority Required procedures

				alone or in combination with corticosteroids, for a minimum of 3 months. Patient must be under 18 years of age. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: (a) an active joint count of at least 20 active (swollen and tender) joints; OR (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). 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. Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction. 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.	
	C14104	P14104		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 be under 30kg; AND	Compliance with Authority Required procedures - Streamlined Authority Code 14104

				Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C14121	P14121		Systemic juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of a new treatment cycle after a break of more than 12 months in a patient weighing less than 30 kg) Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have had a break in treatment of 12 months or more from this drug for this condition; AND Patient must have polyarticular course disease and the condition must have at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); (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); OR Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN); AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must be under 18 years of age. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:	Compliance with Authority Required procedures

				(a) the date of assessment of severe active systemic juvenile idiopathic arthritis. The following reports must be documented in the patient's medical records where appropriate: (a) pathology reports detailing C-reactive protein (CRP) level and platelet count. The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application. 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 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.	
	C14147	P14147		Systemic juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months in a patient weighing at least 30 kg) Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have had a break in treatment of 12 months or more from this drug for this condition; AND Patient must have polyarticular course disease and the condition must have at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); (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); OR Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN); AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must be under 18 years of age. 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 systemic juvenile idiopathic arthritis. The following reports must be documented in the patient's medical records where appropriate: (a) pathology reports detailing C-reactive protein (CRP) level and platelet count. The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application. 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	Compliance with Authority Required procedures

				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 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.	
	C14150	P14150		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 be 30kg or over; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	Compliance with Authority Required procedures - Streamlined Authority Code 14150
	C14153	P14153		Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.	Compliance with Authority Required procedures

				Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints. Active joints are defined as: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints. Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction. 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) 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.	
	C14164	P14164		Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:	Compliance with Authority Required procedures - Streamlined Authority Code 14164

				(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. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C14166	P14166		Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to	Compliance with Authority Required procedures

				change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C14174	P14174		Active giant cell arteritis Initial treatment Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis. Patient must have clinical symptoms of active giant cell arteritis in the absence of any other identifiable cause; AND Patient must have an ESR equal to or greater than 30 mm/hour within the past 6 weeks; OR Patient must have a CRP equal to or greater than 10 mg/L within the past 6 weeks; OR Patient must have active giant cell arteritis confirmed by positive temporal artery biopsy or imaging; AND Patient must have had a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis; AND Patient must have had temporal artery biopsy revealing features of giant cell arteritis at diagnosis; OR Patient must have had evidence of large-vessel vasculitis by magnetic resonance (MR) or computed tomography (CT) angiography or PET/CT; OR Patient must have had evidence of positive temporal artery halo sign by ultrasound (US) at diagnosis; AND The treatment must be in combination with a tapering course of corticosteroids; AND The treatment must not exceed 52 weeks in total including initial and continuing applications. Patient must be aged 50 years or older. Clinical symptoms of giant cell arteritis at diagnosis include unequivocal cranial symptoms of giant cell arteritis (new onset localized headache, scalp tenderness, temporal artery tenderness or decreased pulsation, ischemia related vision loss, or otherwise unexplained mouth or jaw pain upon mastication); or symptoms of polymyalgia rheumatica, defined as shoulder and/or hip girdle pain associated with inflammatory morning stiffness. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS and must include: (a) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has active giant cell arteritis including pathology reports outlining the patient's ESR or CRP levels within the last 6 weeks, or positive temporal artery biopsy or imaging; and (b) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has been diagnosed with giant cell arteritis with a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater	Compliance with Written Authority Required procedures

				than 24.5 mg/L at diagnosis. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
	C14175	P14175		Systemic juvenile idiopathic arthritis Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months in a patient weighing at least 30 kg) Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. An adequate response to treatment is defined as: (a) in a patient with polyarticular course disease: (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%: - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or - 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). (b) in a patient with refractory systemic symptoms: (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dose of corticosteroid by at least 30% from baseline. The assessment of response to treatment must be documented in the patient's medical records. The following reports must be documented in the patient's medical records where appropriate: (a) pathology reports detailing C-reactive protein (CRP) level and platelet count. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retrial 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 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-	Compliance with Authority Required procedures

				subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14179	P14179		Systemic juvenile idiopathic arthritis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. An adequate response to treatment is defined as: (a) in a patient with polyarticular course disease: (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%: - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or - 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). (b) in a patient with refractory systemic symptoms: (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dose of corticosteroid by at least 30% from baseline. 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 measurements of disease severity provided with the initial treatment application. The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records. At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised. 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. The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment. If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 14179

	C14182	P14182		Systemic juvenile idiopathic arthritis Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months in a patient weighing less than 30 kg) Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. An adequate response to treatment is defined as: (a) in a patient with polyarticular course disease: (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%: - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or - 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). (b) in a patient with refractory systemic symptoms: (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dose of corticosteroid by at least 30% from baseline. The assessment of response to treatment must be documented in the patient's medical records. The following reports must be documented in the patient's medical records where appropriate: (a) pathology reports detailing C-reactive protein (CRP) level and platelet count. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retrial 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 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	Compliance with Authority Required procedures

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

(a) *omit:*

	C8750	P8750		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate	Compliance with Written Authority Required procedures

				biological medicine.	

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

	C14185	P14185		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this 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	Compliance with Written Authority Required procedures

				for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

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

(a) *omit:*

	C10376	P10376		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, conducted within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to	Compliance with Written Authority Required procedures

				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. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

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

	C14170	P14170		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence	Compliance with Written Authority Required procedures

				therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, conducted within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

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

omit:

	C13020			Waldenstrom macroglobulinaemia Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 July 2022; AND The condition must have relapsed or been refractory to at least one prior chemo-immunotherapy, prior to having initiated non-PBS-subsidised treatment with this drug for this condition; OR Patient must have been unsuitable for treatment with chemo-immunotherapy, defined by a Cumulative Illness Rating Scale of 6 or greater, if untreated (i.e. treatment-naive) for this condition prior to initiating non-PBS-subsidised treatment with this drug; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving non-PBS-subsidised treatment with this drug for this condition; AND Patient must have been untreated with a Bruton's tyrosine kinase inhibitor for this condition prior to initiating non-PBS-subsidised treatment with this drug; OR Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent	Compliance with Authority Required procedures

				treatment withdrawal, when non-PBS-subsidised treatment was initiated for this condition.	

[90] Schedule 5

insert as first entry:

Acalabrutinib	GRP-27509	Capsule 100 mg	Oral	Calquence
		Tablet 100 mg	Oral	CALQUENCE

[91] Schedule 5, entry for Adalimumab

omit:

	GRP-27087	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Yuflyma
		Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Amgevita Hadlima Hyrimoz Idacio

[92] Schedule 5, after entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[GRP-27088]*

insert:

	GRP-27089	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Yuflyma
		Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Amgevita Hadlima Hyrimoz Idacio

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

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

(b) *omit from the column headed "Brand":* **Esomeprazole Sandoz**

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

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

(b) *omit from the column headed "Brand":* **Esomeprazole Sandoz**

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

omit from the column headed "Brand": **Ondansetron ODT GH**

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

omit from the column headed "Brand": **Ondansetron ODT GH**

[97] **Schedule 5, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg *[GRP-16933]***

omit from the column headed "Brand": **Ondansetron ODT GH**

[98] **Schedule 5, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg *[GRP-17042]***

omit from the column headed "Brand": **Ondansetron ODT GH**

[99] **Schedule 5, entry for Rizatriptan in the form Tablet (orally disintegrating) 10 mg (as benzoate) *[GRP-17623]***

omit from the column headed "Brand": **Rizatriptan-AU**