

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

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#### 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									

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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   56   5   56     C12495 C12500   C12495 C12500	Oral CALQUENCE AP MP C10652 C12481 56 5 56 C12495 C12500
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#### [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	P11852 P11854	2	3	2	
					MP	C9715 C11713 C11715 C11716 C11717 C11761 C11767 C11852 C11853 C11854 C11855 C11903 C11966		2	5	2	
					MP	C14107 C14136		2	5	2	C(100)
	Injection 20 mg in 0.4 mL pre- filled syringe	Injection	Amgevita	ХТ	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	P11852 P11854	2	3	1	
				MP	C9715 C11579 C11713 C11715 C11716 C11717 C11718 C11761 C11767 C11852 C11853 C11854 C11855 C11903 C11966	P11853 P11903	2	5	1	
				MP	C14107 C14136		2	5	1	C(100)
Injection 40 mg in 0.4 mL pre- filled pen	Injection	Humira	VE	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
		Yuflyma	EW	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
		Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 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 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 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12174 C12175	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 P9715 P11709   C9386 C9715 P11715 P11716   C11107 C11704 P11759 P11761   C11709 C11711 P11852 P11854   C11709 C11711 P11855 P12098   C11716 C11717 P12101 P12147   C11720 C11759 P13602 P13609   C11761 C11767 C11852 C11853   C11861 C11865 C11861 C11865   C11861 C11903 C11906 C11966   C12098 C12101 C12122 C12123   C12131 C12147 C12155   C12156 C12157 C12158 C12174   C12175 C12176 C12190   C12194 C12212 C12214 C12228   C12234 C12240 C12272 C12273   C12275 C12315 C12336 C13550	2 2	2

		C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683				
Yufiyma	EW MP	C13682 C13683 C13694 C14058 C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11770 C11759 C11761 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 C12100 C12194 C12228 C12234 C12255 C1235 C1235 C1236 C1255 C12356 C1255 C12356 C13550 C13556 C13599 C13602 C13606 C13607	P11852 P11854 P11855 P12098 P12101 P12147	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 C12177 C12158 C12177 C12189 C12190 C12194 C12212 C12214 C1228 C12234 C12240 C12272 C12273 C12275 C12315 C1236 C13550 C13602 C13606 C13607 C13609 C13612 C13681 C13682 C13683 C13694 C14058	P12194 P13550 P13599 P13606 P13648 P13650 P13681 P13682	2	3	2
Yuflyma		MP	C8638 C9064	P8638 P9064	2	3	2

		C11107 C11523	P12131 P12174				
			P12194 P13550				
			P13599 P13606				
			P13648 P13650				
			P13681 P13682				
			P13694 P14058				
		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					
Humira	VE MP	C8638 C9064	P11107 P12155	2	4	2	
		C9386 C9715	P12212 P13556				
			P13607 P13612				
		C11709 C11711					
			F 13003				

9

		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					
		C12146 C12155 C12156 C12157					
		C12158 C12157					
		C12175 C12174					
		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	P11107 P12155	2	4	2	
		C9386 C9715	P12212 P13556				
			P13607 P13612				
		C11524 C11529					
		C11579 C11604					
		C11605 C11606					
		C11631 C11634					
		C11635 C11704					
		C11709 C11711					
		C11713 C11715					
		C11716 C11717					
							1
		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			
Humira	VE MP	C8638 C9064 P11704 P11711	2	5	2
		C9386 C9715 P11717 P11720			
		C11107 C11704 P11767 P11769			
		C11709 C11711 P11772 P11853			
		C11713 C11715 P11865 P11867			
		C11716 C11717 P11903 P11906			
		C11720 C11759 P11966 P12122			
		C11761 C11767 P12123 P12148			
		C11769 C11772 P12156 P12157			
		C11852 C11853 P12158 P12175			
		C11854 C11855 P12176 P12189			
		C11861 C11865 P12190 P12214			
		C11867 C11903 P12228 P12234			
		C11906 C11966 P12240			

		MD	C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C1224 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13681 C13682 C13683 C13694 C14058		2	-	2	0(100)
Yuflyma	EW	MP	C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852	P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12175 P12176 P12189 P12190 P12214 P12228 P12234	2	5	2 2	C(100)

			C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12224 C12273 C12275 C12315 C12336 C13550 C13556 C13559 C13602 C13606 C13607 C13609 C13612 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 C11864 C11855 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12174	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				
Yuflyma	EW MP	C13694 C14058 C8638 C9064 P12273 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 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12199 C12190 C12194	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 P12272 P12315 4 5 2   C9386 C9715 C11107 C11704 11107 C11704 11107 C11704   C11709 C11711 C11713 C11715 11716 C11717 11720 C11759   C11761 C11767 C11769 C11772 11854 C11855 11854 C11855   C11852 C11853 C11854 C11865 11867 C11903 11906 C11966   C12098 C12101 C12122 C12123 12131 C12147 12155   C12156 C12157 C12158 C12174 12175 C12176   C12234 C12240 C12234 C12240 12234 C12240   C12234 C12240 C12275 C12315 12336 C13550   C13556 C13599 C13602 C13606 13602 C13606	

			C13607 C13609				
			C13612 C13648				
			C13650 C13681				
			C13682 C13683				
			C13694 C14058				
Yuflyma	EW	MP	C8638 C9064	P11529 P12272	4	5	2
ranyma			C9386 C9715	P12315	•	U	-
			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 C12121				
			C12123 C12131 C12147 C12148				
			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 C11906 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12177 C12158 C12177 C12189 C12190 C12194 C12212 C1224 C1228 C12234 C12240 C12272 C12273 C12275 C12315 C13556 C13559 C13602 C13608 C13607 C13609 C13612 C13681 C13682 C13683 C13694 C14058	P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336	6	0	2
Yuflyma	EW	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529	P11715 P11716 P11759 P11761	6	0	2

					C11570 C11604	P11855 P12098				
					C11605 C11606					
						P12275 P12336				
						P13602 P13609				
					C11709 C11711	F 13002 F 13009				
					C11713 C11715					
					C11716 C11717					
					C11718 C11717					
					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					
Injection 40 mg in 0.4 mL pre-	Injection	Humira	VE	MP	See Note 3	See Note 3	See Note	See Note	2	C(100)
filled syringe	-						3	3		· · /
			_				_	_	_	
		Yuflyma	EW	MP	See Note 3	See Note 3		See Note	2	C(100)
							3	3		

Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C1224 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13608 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 C12158 C12176 C12189 C12190 C12194 C12212 C1224 C12288 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 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	P11852 P11854 P11855 P12098	2	2	2

C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240	
C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228	
C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228	
C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228	
C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228	
C12189 C12190 C12194 C12212 C12214 C12228	
C12194 C12212 C12214 C12228	
C12214 C12228	
C12234 C12240	
C13550 C13556	
C13599 C13602	
C13606 C13607	
C13609 C13612	
C13648 C13650	
C13681 C13682	
C13683 C13694	
C14058	
Yuflyma EW MP C8638 C9064 P9715 P11709 2 2 2	
C9386 C9715 P11715 P11716	
C11107 C11523 P11759 P11761	
C11524 C11579 P11852 P11854	
C11604 C11605 P11855 P12098	
C11606 C11631 P12101 P12147	
C11634 C11635 P13602 P13609	
C11704 C11709	
C11711 C11713	
C11715 C11716	
C11717 C11718	
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Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11720 C11759	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	P8638 P9064	2	3	2
ranyma			C9386 C9715	P9386 P11861	-	U	-
			C11107 C11523				
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Humira	VE	MP	C8638 C9064	P11107 P12155	2	4	2
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		C9386 C9715	P12212 P13556			
			P13607 P13612			
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Yuflyma	EW MP	C8638 C9064	P11107 P12155 2	4	2	
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			C13609 C13612					
			C13648 C13650					
			C13681 C13682					
			C13683 C13694					
			C14058					
Humira	VE		C8638 C9064	P11704 P11711	2	5	2	
Humira	VE	MP	C9386 C9715	P11704 P11711 P11717 P11720	Z	5	2	
			C11107 C11704					
			C11709 C11711					
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				F 12240				

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			C13681 C13682 C13683 C13694					
			C13003 C13094 C14058					
			014030					
		MP	C14107 C14136		2	5	2	C(100)
Yuflyma	EW	MP	C8638 C9064	P11523 P11524	2	5	2	
			C9386 C9715	P11579 P11604				
			C11107 C11523 C11524 C11579					
			C11604 C11605					
			C11606 C11631					
			C11634 C11635					
			C11704 C11709					
			C11711 C11713	P11772 P11853				
			C11715 C11716					
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			C11720 C11759					
			C11761 C11767					
			C11769 C11772 C11852 C11853					
			C11854 C11855					
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			C11867 C11903					
			C11906 C11966					
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			C12131 C12147					
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			$\begin{array}{c} C12158\ C12174\\ C12175\ C12176\\ C12189\ C12190\\ C12194\ C12212\\ C12214\ C12228\\ C12234\ C12240\\ C13550\ C13556\\ C13599\ C13602\\ C13606\ C13607\\ C13609\ C13612\\ C13648\ C13650\\ C13681\ C13682\\ C13683\ C13694\\ C14058\\ \end{array}$					
		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	P11852 P11854 P11855 P12098 P12101 P12147	6	0	2	

		C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
Yuflyma	EW M	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 C11903 C12098 C12101 C12122 C12123 C12156 C12157 C12156 C12157 C12158 C12174 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12202 C12194 C12212 C12214 C1228 C1234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13681 C13682 C13683 C13694	P11852 P11854 P11855 P12098 P12101 P12147	6	0	2

					C14058					
Injection 40 mg in 0.8 mL pre- filled pen	Injection	Amgevita	ХТ	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 C11903 C11906 C1208 C1208 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12190 C12194 C12212 C1224 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 C11861 C11865 C11867 C11903 C11906 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12228 C12234 C12240 C12272 C12273 C12275	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 C12157 C12158 C12174 C12155 C12176 C12189 C12176 C12189 C12190 C12194 C12212 C12244 C12228 C12234 C12273 C12236 C12355 C13556	P11713	2	0	2

			C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650				
Ideeia	סע		C13681 C13682 C13683 C13694 C14058	D11713	2	0	2
Idacio	PK I	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529	P11713	2	0	2
			C11579 C11604 C11605 C11606				
			C11631 C11634 C11635 C11704				
			C11709 C11711 C11713 C11715				
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			C11759 C11761 C11767 C11769				
			C11772 C11852 C11853 C11854				
			C11855 C11861 C11865 C11867				
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			C12101 C12122 C12123 C12131				
			C12147 C12148 C12155 C12156				
			C12157 C12158 C12174 C12175				
			C12176 C12189 C12190 C12194				
			C12212 C12214 C12228 C12234				
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			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 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12236 C1236 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650	P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147	2	2	2	

			C13681 C13682				
			C13683 C13694				
			C14058				
Hadlima	RF	MP	C8638 C9064	P9715 P11709	2	2	2
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			C11107 C11523	P11759 P11761			
			C11524 C11529	P11852 P11854			
			C11579 C11604	P11855 P12098			
			C11605 C11606	P12101 P12147			
			C11631 C11634	P13602 P13609			
			C11635 C11704				
			C11709 C11711				
			C11713 C11715				
			C11716 C11717				
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			C11759 C11761				
			C11767 C11769				
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Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2

Idacio	PK	MP	C11524 C11529 C11579 C11604 C11605 C11606	P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2
Amgevita	ХТ	MP	C8638 C9064 C9386 C9715	P8638 P9064 P9386 P11861	2	3	2

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			P12194 P13550				
			P13599 P13606				
			P13648 P13650				
			P13681 P13682				
		C11635 C11704	P13694 P14058				
		C11709 C11711					
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		C11716 C11717					
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		C13681 C13682					
		C13683 C13694					
		C14058					
Hadlima	RF MP	C8638 C9064	P8638 P9064	2	3	2	
-		C9386 C9715	P9386 P11861		-		
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		C13683 C13694					
		C14058					
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Hyrimoz	SZ MP	C8638 C9064	P8638 P9064	2	3	2	
TIYIIIIOZ	SZ IVIF	C9386 C9715	P9386 P11861	2	3	2	
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			P12194 P13550				
			P13599 P13606				
		C11605 C11606	P13648 P13650				

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			C11635 C11704	P13694 P14058			
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			13648 C13650					
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Amgevita	XT M		8638 C9064	P11107 P12155	2	4	2	
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C13683 C13694	
C14058	
Hadlima    RF    MP    C8638 C9064    P11107 P12155    2    4    2	
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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	
C13083 C13094 C14058	
C 14058	
Hyrimoz SZ MP C8638 C9064 P11107 P12155 2 4 2	
C9386 C9715 P12212 P13556	
C11107 C11523 P13607 P13612	
C11524 C11529 P13683	
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				
			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	ΡK	MP	C8638 C9064	P11107 P12155	2	4	2
			C9386 C9715	P12212 P13556			
				P13607 P13612			
			C11524 C11529	P13683			
			C11579 C11604				
			C11605 C11606				
			C11631 C11634				
			C11635 C11704 C11709 C11711				
			C11713 C11715				
			C11716 C11715				
			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 C12228 C12234 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058
Amgevita	XT MP	C8638 C9064    P11523 P11524    2    5    2      C9386 C9715    P11579 P11604                    2    5    2

			C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12199 C12190 C12194 C12222 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P12240				
Hadlima	RF	MP	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	P11635 P11704 P11711 P11717 P11718 P11720 P11767 P11769 P11772 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157	2	5	2	C(100)

			C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13648 C13650 C13681 C13682 C13683 C13694 C14058	P12240				
Hyrimoz	SZ	MP	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	P11718 P11720 P11767 P11769 P11772 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157	2	5	2	C(100)

			C11903 C11906	P12240				
			C11966 C12098					
			C12101 C12122					
			C12123 C12131					
			C12147 C12148					
			C12155 C12156					
			C12157 C12158 C12174 C12175					
			C12174 C12175					
			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)
Idacio	PK	MP	C8638 C9064	P11523 P11524	2	5	2	
			C9386 C9715	P11579 P11604				
			C11107 C11523					
			C11524 C11529					
			C11579 C11604					
			C11605 C11606					
			C11631 C11634 C11635 C11704					
			C11709 C11711					
			C11713 C11715					
			C11716 C11717					
			C11718 C11720					
			C11759 C11761					
			C11767 C11769	P12156 P12157				
			C11772 C11852					
			C11853 C11854					
			C11855 C11861					
			C11865 C11867	P12228 P12234				

		MP	C11903 C11906 C11966 C12098 C12101 C12122 C1213 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 C13681 C13682 C13683 C13694 C1407 C14136		2	5	2	0(400)
Amgevita	XT		C14107 C14136 C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11865 C11861 C11865 C11867	P12273	4	2	2	C(100)

		C11903 C11906				
		C11966 C12098				
		C12101 C12122				
		C12123 C12131				
		C12147 C12148				
		C12155 C12156				
		C12157 C12158 C12174 C12175				
		C12174 C12175				
		C12190 C12194				
		C12212 C12214				
		C12228 C12234				
		C12240 C12272				
		C12273 C12275				
		C12315 C12336				
		C13550 C13556				
		C13599 C13602 C13606 C13607				
		C13609 C13607				
		C13648 C13650				
		C13681 C13682				
		C13683 C13694				
		C13683 C13694 C14058				
		C14058	D.40070		2	<b>^</b>
Hadlima	RF MP	C14058 C8638 C9064	P12273	4	2	2
Hadlima	RF MP	C14058 C8638 C9064 C9386 C9715	P12273	4	2	2
Hadlima	RF MP	C14058 C8638 C9064 C9386 C9715 C11107 C11523	P12273	4	2	2
Hadlima	RF MP	C14058 C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529	P12273	4	2	2
Hadlima	RF MP	C14058 C8638 C9064 C9386 C9715 C11107 C11523	P12273	4	2	2
Hadlima	RF MP	C14058 C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604	P12273	4	2	2
Hadlima	RF MP	C14058 C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704	P12273	4	2	2
Hadlima	RF MP	C14058 C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711	P12273	4	2	2
Hadlima	RF MP	C14058 C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11604 C11635 C11704 C11635 C11704 C11709 C11711 C11713 C11715	P12273	4	2	2
Hadlima	RF MP	C14058 C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11604 C11635 C11704 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717	P12273	4	2	2
Hadlima	RF MP	C14058 C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11604 C11635 C11704 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720	P12273	4	2	2
Hadlima	RF MP	C14058 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	P12273	4	2	2
Hadlima	RF MP	C14058 C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11769	P12273	4	2	2
Hadlima	RF MP	C14058 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	P12273	4	2	2
Hadlima	RF MP	C14058 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 C11769 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861	P12273	4	2	2
Hadlima	RF MP	C14058 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
Hadlima	RF MP	C14058 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 C11855 C11861 C11865 C11867 C11903 C11906	P12273	4	2	2
Hadlima	RF MP	C14058 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

		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    P12273      C9386 C9715    C11107 C11523      C11524 C11529    C11579 C11604      C11605 C11606    C11631 C11634      C11635 C11704    C11709 C11711      C11713 C11715    C11716 C11717      C11759 C11761    C11759 C11761      C11767 C11769    C11772 C11852      C11853 C11854    C11855 C11861      C11865 C11867    C11903 C11906      C11906 C12098    C12101 C12122      C12101 C12131    C12131	3 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 C13602				
			C13609 C13612				
			C13648 C13650				
			C13681 C13682				
			C13683 C13694				
			C14058				
Idacio	PK	MP	C8638 C9064	P12273	4	2	2
			C9386 C9715				
			C11107 C11523				
			C11524 C11529				
			C11718 C11720				
			C11853 C11854				
			C11855 C11861				
			C11865 C11867				
			C11865 C11867 C11903 C11906				
			C11865 C11867 C11903 C11906 C11966 C12098				
			C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122				
			C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131				
			C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122				
			C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854				

			C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 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 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 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  P11529 P12272 4  5  2    C9386 C9715  P12315  P12315    C11107 C11523  C11524 C11529	

			C12212 C12214				
			C12228 C12234				
			C12240 C12272 C12273 C12275				
			C12315 C12275				
			C13550 C13556				
			C13599 C13602				
			C13606 C13607				
			C13609 C13612				
			C13648 C13650				
			C13681 C13682				
			C13683 C13694 C14058				
			014030				
Hyrimoz	SZ	MP	C8638 C9064	P11529 P12272	4	5	2
			C9386 C9715	P12315			
			C11107 C11523 C11524 C11529				
			C11524 C11529 C11579 C11604				
			C11605 C11604				
			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				
			C12101 C12122 C12123 C12131				
			C12147 C12148				
			C12155 C12156				
			C12157 C12158				
			C12174 C12175				
			C12176 C12189				
			C12190 C12194				
			C12212 C12214 C12228 C12234				
			012220 012234				

			C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694				
Idacio	РК	MP	C14058 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 C11861 C11865 C11867 C11903 C11906 C1298 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12222 C12244 C12228 C12245 C12273 C12275	4	5	2	

			C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694	
Amgevita	XT	MP	C14058 C8638 C9064 P9715 P11709 6 0 C9386 C9715 P11715 P11716 C11107 C11523 P11759 P11761 C11524 C11529 P11852 P11854 C11579 C11604 P11855 P12098 C11605 C11606 P12101 P12147 C11631 C11634 P12275 P12336 C11635 C11704 P13602 P13609 C11709 C11711 C11718 C11720 C11759 C11761 C11759 C11761 C11767 C11769 C11772 C11852 C11855 C11861 C11865 C11867 C11903 C11906 C1208 C12098 C12101 C12122 C12133 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12222 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556	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 C11861 C11865 C11867 C11903 C11906 C11906 C12098 C12101 C12122 C12133 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12174 C12199 C12174 C12199 C12190 C12194 C12212 C12214 C12228 C12234 C12235 C12336 C13550 C13556 C13599 C13602 C13606 C13607	P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336	6	0	2

			C13609 C13612				
			C13609 C13612 C13648 C13650				
			C13681 C13682				
			C13683 C13694				
			C14058				
Hyrimoz	SZ	MP	C8638 C9064		6	0	2
			C9386 C9715	P11715 P11716			
			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				
			C12176 C12189 C12190 C12194				
			C122190 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	DK	MP	C8638 C9064	P9715 P11709	6	0	2
Iuacio	FK		C9386 C9715	P11715 P11716	0	0	2
			C11107 C11523				
			C11524 C11529				
			C11579 C11604				
			C11605 C11606				
			C11631 C11634				
			C11635 C11704				
			C11709 C11711	F 13002 F 13009			
			C11713 C11715				
			C11716 C11717				
			C11718 C11720				
			C11759 C11761				
			C11767 C11769				
			C11772 C11852				
			C11853 C11854				
			C11855 C11854				
			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					
Injection 40 mg in 0.8 mL pre- filled syringe	Injection	Amgevita	ХТ	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 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12148 C12155 C12169 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				
			C13003 C13034				
				D11710		•	2
Hadlima	RF	MP	C8638 C9064 C9386 C9715	P11713	2	0	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				
			C12156 C12157 C12158 C12174				
			C12175 C12176				
			C12189 C12190				
			C12194 C12212				
			C12214 C12228				
			C12234 C12240				
			C13550 C13556				
			C13599 C13602 C13606 C13607				
			C13609 C13612				
			C13648 C13650				
			013040 013030				

C13681 C13682 C13683 C13694 C14058 Hyrimoz SZ MP C8638 C9064 P11713 2 0 2 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11604 C11605 C11604 C11605 C11604 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11770 C11776 C11776 C11776 C11776 C11776 C11769 C11775 C11769 C11772 C11852 C11853 C11854 C11855								
C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11762 C11772 C11762 C11772 C11763 C11772 C11763 C11772 C11763 C11772 C11854 C11855				C13683 C13694				
C 11861 C 11865 C 11867 C 11903 C 11906 C 11966 C 12098 C 12101 C 12122 C 12123 C 12131 C 12147 C 12148 C 12155 C 12156 C 12157 C 12158 C 12174 C 12175 C 12176 C 12189 C 12190 C 12194 C 12212 C 12234 C 12240 C 12234 C 12240 C 123556 C 13559 C 13656 C 13569 C 13602 C 13681 C 13682 C 13681 C 13682 C 13684 C 13650 C 13684 C 13694 C 14058	Hyrimoz	SZ	MP	C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C1224 C12288 C12234 C12240 C13550 C13556 C13599 C13602 C13608 C13694	P11713	2	0	2
Idacio PK MP C8638 C9064 P11713 2 0 2	Idacio	ΡK	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	P9715 P11709	2	2	2
Angevia		1711	C9386 C9715	P11715 P11716	4	4	2
				P11759 P11761			
				P11852 P11854			
				P11855 P12098			
				P12101 P12147			
			011000 011001				

		C11634 C11635	P13602 P13609			
		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				
		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	P9715 P11709	2	2	2
		C9386 C9715	P11715 P11716			
		C11107 C11523	P11759 P11761			
		C11524 C11579	P11852 P11854			
			P11855 P12098			
			P12101 P12147			
			P13602 P13609			
		C11704 C11709				
		C11711 C11713				
		C11715 C11716				
		C11717 C11718				

			C11720 C11759					
			C11761 C11767					
			C11769 C11772					
			C11852 C11853					
			C11854 C11855					
			C11861 C11865					
			C11867 C11903					
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			C12098 C12101					
			C12122 C12123					
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			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					
			C140E0					
			C14058					
Hyrimoz	SZ	MP	C8638 C9064		2	2	2	
Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715	P11715 P11716	2	2	2	
Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523	P11715 P11716 P11759 P11761	2	2	2	
Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579	P11715 P11716 P11759 P11761 P11852 P11854	2	2	2	
Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605	P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098	2	2	2	
Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631	P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147	2	2	2	
Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635	P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147	2	2	2	
Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709	P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147	2	2	2	
Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713	P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147	2	2	2	
Hyrimoz	SZ	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716	P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147	2	2	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	P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147	2	2	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	P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147	2	2	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	P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147	2	2	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	P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147	2	2	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	P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147	2	2	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	P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147	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 C1224 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
Idacio	РК	MP	C11524 C11579 C11604 C11605 C11606 C11631	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 C12244 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 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 C11770 C11759 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12174 C12175 C12176	P12194 P13550 P13599 P13606 P13648 P13650 P13681 P13682	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  P8638 P9064  2  3  2    C9386 C9715  P9386 P11861  C1107 C11523  P12131 P12174    C11524 C11579  P12194 P13550  C11604 C11605  P13599 P13606    C11604 C11635  P13648 P13650  C11634 C11635  P13681 P13682    C11704 C11709  P13694 P14058  C11711 C11713    C11715 C11716  C11772 C11769  C11761 C11767    C11760 C11772  C11852 C11853  C11854 C11855    C11864 C11865  C11867 C11903  C11906    C1208 C12101  C12122 C12123  C12156 C12157    C12158 C12174  C12175 C12176  C12189 C12101    C12189 C12101  C12199 C12174  C12175 C12176    C12189 C12101  C12234 C12228  C12234 C12240    C12234 C12240  C13550 C13556  C13550 C13556

			C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058				
Hyrimoz	SZ	MP	C11604 C11605 C11606 C11631 C11634 C11635	P8638 P9064 P9386 P11861 P12131 P12174 P12194 P13550 P13599 P13606 P13648 P13650 P13681 P13682 P13694 P14058	2	3	2

			C13683 C13694				
			C14058				
Idacio	РК	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C117717 C11778 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12156 C12157 C12156 C12157 C12158 C12174 C12189 C12100 C12194 C12212 C12214 C1228 C12234 C12240 C13550 C13556 C13609 C13612 C13648 C13607 C13609 C13612 C13648 C13694 C14058	P12194 P13550 P13599 P13606 P13648 P13650 P13681 P13682	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 C11715 C11716 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11864 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12177 C12189 C12190 C12194 C12212	P13607 P13612 P13683				
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Hadlima	RF MP	C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058 C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635	P11107 P12155 2 P12212 P13556 P13607 P13612 P13683	4	2		

C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903	
C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903	
C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903	
C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903	
C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903	
C11769 C11772 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903	
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C11854 C11855 C11861 C11865 C11867 C11903	
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C11867 C11903	
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C12158 C12174	
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C12189 C12190	
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C12234 C12240	
C13550 C13556 C13599 C13602	
C13606 C13602	
C13609 C13612	
C13648 C13650	
C13681 C13682	
C13683 C13694	
C14058	
Hyrimoz SZ MP C8638 C9064 P11107 P12155 2 4 2	
C9386 C9715 P12212 P13556	
C11107 C11523 P13607 P13612	
C11524 C11579 P13683	
C11604 C11605	
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C11634 C11635 C11704 C11709	
C11714 C11709	
C11715 C11715	
C11713 C11718	
C11720 C11759	
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			C11761 C11767					
			C11769 C11772					
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			C11854 C11855					
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			C12158 C12174					
			C12175 C12176					
			C12189 C12190					
			C12194 C12212					
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			C13599 C13602					
			C13606 C13602					
			C13609 C13612					
			C13648 C13650					
			C13681 C13682					
			C13683 C13694					
			C14058					
			0.1000					
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			C9386 C9715	P12212 P13556				
			C11107 C11523	P13607 P13612				
			C11524 C11579	P13683				
			C11604 C11605					
			C11604 C11605 C11606 C11631					
			C11606 C11631 C11634 C11635					
			C11606 C11631 C11634 C11635 C11704 C11709					
			C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713					
			C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716					
			C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718					
			C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759					
			C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767					
			C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772					
			C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853					
			C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853 C11854 C11855					
			C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11767 C11769 C11772 C11852 C11853					

		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       P11523 P11524       2       5       2         C9386 C9715       P11579 P11604       1107 C11523       P11605 P11606         C11524 C11579       P11631 P11634       11635 P11704         C11604 C11605       P11635 P11704       11635 P11718 P11720         C11634 C11635       P11718 P11720       11704 C11709       11767 P11769         C11714 C11709       P11767 P11769       11715 C11776       11865 P11867         C11720 C11759       P11966 P12122       11761 C11767       P12123 P12148         C11769 C11772       P12156 P12157       11852 C11853       P12158 P12175         C11854 C11855       P12176 P12189       11861 C11865       P1220 P12214         C11867 C11903       P12228 P12234       11906 C11966       P12240         C12098 C12101       1222       12131 C12147       12131 C12147

			C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13609 C13612 C13609 C13612 C13681 C13682 C13683 C13694 C14058					
		MP	C14107 C14136		2	5	2	C(100)
Hadlima	RF	MP		11631 P11634 11635 P11704 11711 P11717 11718 P11720 11767 P11769 11772 P11853 11865 P11867 11906 P12122 12123 P12148 12156 P12157 12158 P12175 12158 P12175 12176 P12189 12190 P12214 12228 P12234	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         P11523 P1152           C9386 C9715         P11579 P1160           C11107 C11523         P11605 P1160           C11524 C11579         P11635 P1170           C11604 C11605         P11635 P1170           C11606 C11631         P11711 P1171           C11634 C11635         P11772 P1185           C11704 C11709         P11767 P1176           C11715 C11716         P11865 P1186           C11717 C11718         P11903 P1190           C11720 C11759         P11966 P1212           C11761 C11767         P12123 P1214           C11762 C11772         P12158 P1217           C11852 C11853         P12176 P1218           C11852 C11853         P12176 P1218           C11852 C11853         P12176 P1218           C11861 C11865         P12190 P1221           C11861 C11865         P12190 P1221           C11806 C11906         P12240           C12098 C12101         C12028 P1223           C12131 C12147         C12148 C12155           C12156 C12157         C12158 C12174           C12194 C12210         C12194 C12212	4 6 4 4 7 0 9 3 7 6 2 8 7 5 9 4	5	2	

		MP	C12214 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694 C14058 C14107 C14136		2	5	2	C(100)
Idacio	PK	MP		P11631 P11634 P11635 P11704 P11711 P11717 P11718 P11720 P11767 P11769 P11772 P11853 P11865 P11867 P11906 P12122 P12123 P12148 P12156 P12157 P12158 P12175 P12176 P12189 P12190 P12214 P12228 P12234	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	C11604 C11605 C11606 C11631	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		6	0	2	
			C9386 C9715	P11715 P11716				
			C11107 C11523					
				P11852 P11854				
				P11855 P12098				
				P12101 P12147				
				P13602 P13609				
			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	C11604 C11605 C11606 C11631	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P12101 P12147 P13602 P13609	6	0	2
Idacio	PK	MP	C11524 C11579	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098	6	0	2

				C11606 C11631	P12101 P12147				
					P13602 P13609				
				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					
				C12098 C12101 C12122 C12123					
				C12122 C12123					
				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					
Injection 80 mg in 0.8 mL pre- Injecti	on Humira	VE	MP		P12103 P12105 1	(	)	1	
filled pen					P12153 P12155				
				C11762 C11763	P12161 P12212				
				C11852 C11854					
				C11855 C12103					
				C12105 C12152					
				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	P11759 P11761 P11762 P11763 P11852 P11854 P11855 P12152 P12229 P12275	3	0	1
Injection 80 mg in 0.8 mL pre- filled syringe	Injection	Humira	VE MP	C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152	P12153 P12155	1	0	1

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

							00007 00045			-		
			а	Alendronate plus D3-DRLA	RZ	MP NP	C6307 C6315 C6320		4	5	4	
8]		edule 1, Part 1, entry for Ale calciferol	endronic acid with c	blecalciferol in th	e fori	m Tablet	70 mg (as alend	dronate sodiı	ım) with 14	10 micro	grams	
			а	Alendronate plus D3-DRLA	RZ	MP NP	C6306 C6319 C6325		4	5	4	
9]	Sche insert	edule 1, Part 1, after entry fo	or Auranofin in the f	orm Tablet 3 mg								
Avatrom	bopag	Tablet 20 mg	Oral	Doptelet	ZO	MP	See Note 3	See Note 3	See Note 3	See Note 3	30	D(100)
10]		edule 1, Part 1, entry for Aza t in the columns in the order ind		<i>cal order for the col</i> Azacitidine Sandoz			cand": See Note 3	See Note 3		See Note	1	D(100)
			athioprine in the for	n Tablet 25 mg					3	3		
[11]	Sche omit:	· · · ·										
[11]		· · · ·	a	Azathioprine GH	GQ	MP NP			100	5	100	

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#### [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 Inhala breath actuated device containing mouth budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	ation by a h	BiResp Spiromax	ТВ	MP	C7970 C10464 C10538	P10464	1	2	1
					NP	C7970 C10464	P10464	1	2	1
		а	DuoResp Spiromax	EV	MP	C7970 C10464 C10538	P10464	1	2	1
					NP	C7970 C10464	P10464	1	2	1
		а	Rilast TURBUHALER 200/6	ZA	MP	C7970 C10464 C10538	P10464	1	2	1
					NP	C7970 C10464	P10464	1	2	1

а	Symbicort Turbuhaler 200/6	AP	MP	C7970 C10464 C10538	P10464	1	2	1
			NP	C7970 C10464	P10464	1	2	1
а	BiResp Spiromax	тв	MP	C7970 C10464 C10538	P7970 P10538	1	5	1
			NP	C7970 C10464	P7970	1	5	1
а	DuoResp Spiromax	EV	MP	C7970 C10464 C10538	P7970 P10538	1	5	1
			NP	C7970 C10464	P7970	1	5	1
а	Rilast TURBUHALER 200/6	ZA	MP	C7970 C10464 C10538	P7970 P10538	1	5	1
			NP	C7970 C10464	P7970	1	5	1
а	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 Inhalatio breath actuated device containing mouth budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses	nby a	Rilast TURBUHALER 400/12	ZA	MP NP	C7979 C10121	2	5	1
		а	Symbicort TURBUHALER 400/12	AP	MP NP	C7979 C10121	2	5	1
		а	BiResp Spiromax	ТВ	MP NP	C7979 C10121	2	5	2

			;	a DuoResp Spiromax	EV	MP NP	C7979 C10121	2	5	2	
18]		, Part 1, omit entry for Bude budesonide 400 microgram							device		
19]	Schedule 1	, Part 1, entry for Buprenor	phine								
	substitute:										
upreno	rphine	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	а	Bupredermal	ТΧ	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		а	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		а	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		а	Bupredermal	тх	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
		а	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
		а	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
Transdermal patch 10 mg	Transdermal	а	Bupredermal	тх	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		а	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753		2	0	2	
		а	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		а	Bupredermal	ТΧ	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
		а	Buprenorphine Sandoz	SZ	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
		а	Norspan	MF	MP NP	C10748 C10752 C10755 C11753	P11753	4	0	2	
Transdermal patch 15 mg	Transdermal	а	Bupredermal	ТΧ	MP NP	C10748 C10752 C10755 C11753	P10748 P10752 P10755	2	0	2	
		а	Buprenorphine	SZ	MP NP	C10748 C10752	P10748 P10752	2	0	2	

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

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

h	ydrochloride)									
	ablet (sublingual) 2 mg (as ydrochloride)	Sublingual	Subutex	IR	MP NP	C14157	84	2	7	PB(100)
	ablet (sublingual) 8 mg (as ydrochloride)	Sublingual	Subutex	IR	MP NP	C14157	112	2	7	PB(100)

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

substitute:
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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	
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[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	ΗХ	MP	C8774 C8775 C8776 C8780 C8827 C11310	P8774 P8775	30	1	30
			NP	C8774 C8775 C8776 C8780	P8774 P8775	30	1	30

(c) *omit*:

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

C8827

					NP	C8774 C8775 C8776 C8780 C8827	P8776 P8780 P8827	30	5	30
	(d)	omit:								
			Esomeprazole SZ	ΗХ	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	ΗХ	MP	C8774 C8775 C8776 C8780 C8827 C11310	P11310	60	5	30
[33]	Sche	dule 1, Part 1, entry for Esomeprazole in the for	rm Tablet (enterio	coa	ted) 40 m	ng (as magnesi	um 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	ΗX	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	ΗX	MP	C8777 C8778 C8902 C11370	P11370	60	5	30	
[34]	Sche	dule 1,	Part 1, entry for Etanercep	t									
	substit	tute:											
Etanercep	pt		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	P12327 P12434				
	C9386 C9388 C9410 C9429	P12327 P12434 P12457 P13532				
	C9473 C9487	P13533 P13535				
	C9502 C9554	P13537 P13538				
		P13539 P13540				
		P13542 P13593				
		P13598 P13646				
		P13647 P13707				
	C12289 C12327	P14108				
	C12434 C12457					
	C13532 C13533					
	C13535 C13537					
	C13538 C13539					
	C13540 C13542					
	C13593 C13598					
	C13646 C13647					
	C13707 C14108					
MP	C7289 C8638	P7289 P8662	2	5	1	
	C8662 C8692	P8692 P8718				
	C8718 C8839	P8839 P8842				
	C8842 C8873	P8873 P8879				
	C8879 C9064	P9081 P9123				
	C9081 C9123	P9140 P9162				
	C9140 C9162	P9377 P9380				
	C9377 C9380	P9487 P9502				
	C9386 C9388	P9554				
	C9410 C9429 C9473 C9487					
	C9473 C9487 C9502 C9554					
	C9502 C9554 C11107 C12164					
	C12260 C12261					
	C12260 C12261 C12262 C12265					
	C12262 C12265					
	C12289 C12327					
	C12434 C12457					
	C13532 C13533					
	C13535 C13537					
	C13538 C13539					
	C13540 C13542					
	C13593 C13598					
	C13646 C13647					
	C13707 C14108					

Injection 50 mg in 1 mL single use auto-injector, 4	e 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 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	P13647 P13707	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 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

				MP	C12434 C12457 C13532 C13533 C13535 C13537 C13538 C13539 C13540 C13542 C13593 C13598 C13646 C13647 C13707 C14108 C14154 C14155		1	5	1	C(100)
Injections 50 mg in 1 mL s use pre-filled syringes, 4	ngle Injectior	n Enbrel	PF	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	C(100)
		Brenzys	RF	MP	$\begin{array}{c} C7276 \ C7289 \\ C8638 \ C8662 \\ C8692 \ C8718 \\ C8839 \ C8842 \\ C8873 \ C8955 \\ C9064 \ C9081 \\ C9123 \ C9140 \\ C9156 \ C9162 \\ C9410 \ C9429 \\ C9481 \ C9487 \\ C9502 \ C9554 \\ C11107 \ C13532 \\ C13533 \ C13535 \\ C13537 \ C13538 \\ C13539 \ C13540 \\ C13542 \ C13646 \\ C13647 \ C13707 \\ C14108 \end{array}$	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 C13533 C13535 C13537 C13540 C13542 C13593 C13598 C13646 C13647 C13707 C14108	P13542 P13593 P13598 P13646 P13647 P13707			
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 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":

	а	Pharmacor C 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":

		а	FINGOLIS	LR	MP	C10162 C10172	28	5	28
	chedule 1, Part 1, entry for Fluticasor ) micrograms per dose, 120 doses (C			ressuris	ed inha	lation containing fluticas	sone propion	ate	
om	nit from the column headed "Circumstances	s" (all instances)	): C13917		substit	ute (all instances): C14180			
-	chedule 1, Part 1, entry for Golimuma <i>Repeats: 3]</i>	b in the form	Injection 50 n	ng in 0.5	5 mL sin	gle use pre-filled pen <i>[M</i>	aximum Qua	ntity: 1;	Number
(a)	) omit from the column headed "Circum	nstances": C874	41						
(b)	) insert in numerical order in the colum	n headed "Circi	umstances": C1	4171					
(c)	) omit from the column headed "Purpos	ses": <b>P8741</b>							
(d)	) insert in numerical order in the colum	in headed "Purp	oses": <b>P14171</b>						
	chedule 1, Part 1, entry for Golimuma	b in the form	Injection 50 n	ng in 0.5	5 mL sin	gle use pre-filled pen [M	aximum Qua	ntity: 1;	Number
of	Repeats: 5]								
of (a)		nstances": C874	41						
	) omit from the column headed "Circun			4171					
(a) (b) ] Sc	) omit from the column headed "Circun	n headed "Circi	umstances": C1		5 mL sin	gle use pre-filled syring	e [Maximum	Quantity	: 1;
(a) (b) ] Sc	<ul> <li>omit from the column headed "Circun insert in numerical order in the colum chedule 1, Part 1, entry for Golimuma umber of Repeats: 3]</li> </ul>	nn headed "Circu Ib in the form	umstances": C1 Injection 50 n		5 mL sin	gle use pre-filled syring	e [Maximum	Quantity	: 1;
(a) (b) ] Sc <i>Nu</i>	<ul> <li>omit from the column headed "Circum insert in numerical order in the column chedule 1, Part 1, entry for Golimuma umber of Repeats: 3]</li> <li>omit from the column headed "Circum</li> </ul>	nn headed "Circi b in the form nstances": C874	umstances": C1 Injection 50 n 41	ng in 0.5	5 mL sin	gle use pre-filled syring	e [Maximum	Quantity	: 1;
(a) (b) ] Sc <i>Nu</i> (a)	<ul> <li>omit from the column headed "Circundination of the column headed" (Circundination of the column headed (Circundination of the column headed (Circundination of the column headed (Circundination)) insert in numerical order in the column headed (Circundination)</li> </ul>	nn headed "Circu <b>b in the form</b> nstances": <b>C87</b> 4 nn headed "Circu	umstances": C1 Injection 50 n 41	ng in 0.5	5 mL sin	gle use pre-filled syring	e [Maximum	Quantity	: 1;
(a) (b) ] Sc <i>Nu</i> (a) (b)	<ul> <li>omit from the column headed "Circum insert in numerical order in the column chedule 1, Part 1, entry for Golimuma umber of Repeats: 3]</li> <li>omit from the column headed "Circum insert in numerical order in the column omit from the column headed "Purpo.</li> </ul>	nn headed "Circu <b>b in the form</b> nstances": <b>C87</b> 4 nn headed "Circu ses": <b>P8741</b>	umstances": C1 Injection 50 n 41 umstances": C1	ng in 0.5	5 mL sin	gle use pre-filled syring	e [Maximum	Quantity	: 1;
(a) (b) 3 <i>Nu</i> (a) (b) (c) (d) 2] Sc	<ul> <li>omit from the column headed "Circum insert in numerical order in the column chedule 1, Part 1, entry for Golimuma umber of Repeats: 3]</li> <li>omit from the column headed "Circum insert in numerical order in the column omit from the column headed "Purposed"</li> </ul>	in headed "Circi b in the form instances": C874 in headed "Circi ses": P8741 in headed "Purp	umstances": C1 Injection 50 n 41 umstances": C1 ooses": P14171	ng in 0.5  4171			-		
(a) (b) 3 <i>Nu</i> (a) (b) (c) (d) 2] Sc	<ul> <li>omit from the column headed "Circum insert in numerical order in the column chedule 1, Part 1, entry for Golimuma umber of Repeats: 3]</li> <li>omit from the column headed "Circum insert in numerical order in the column omit from the column headed "Purpos insert in numerical order in the column insert in numerical order in the column chedule 1, Part 1, entry for Golimuma umber of Repeats: 5]</li> </ul>	an headed "Circu <b>b in the form</b> Instances": <b>C87</b> 4 In headed "Circu Ises": <b>P8741</b> In headed "Purp Ib in the form	umstances": C1 Injection 50 n 41 umstances": C1 coses": P14171 Injection 50 n	ng in 0.5  4171			-		
(a) (b) 3 (a) (b) (c) (d) 2] Sc <i>Nu</i>	<ul> <li>omit from the column headed "Circum insert in numerical order in the column chedule 1, Part 1, entry for Golimuma umber of Repeats: 3]</li> <li>omit from the column headed "Circum insert in numerical order in the column omit from the column headed "Purpos insert in numerical order in the column chedule 1, Part 1, entry for Golimuma umber of Repeats: 5]</li> <li>omit from the column headed "Circum</li> </ul>	in headed "Circu b in the form instances": C874 in headed "Circu ses": P8741 in headed "Purp ib in the form instances": C874	umstances": C1 Injection 50 n 41 umstances": C1 toses": P14171 Injection 50 n	ng in 0.5 14171 ng in 0.5			-		
(a) (b) Sc Nu (a) (c) (d) 2] Sc Nu (a) (b)	<ul> <li>omit from the column headed "Circum insert in numerical order in the column chedule 1, Part 1, entry for Golimuma umber of Repeats: 3]</li> <li>omit from the column headed "Circum insert in numerical order in the column omit from the column headed "Purpos insert in numerical order in the column chedule 1, Part 1, entry for Golimuma umber of Repeats: 5]</li> <li>omit from the column headed "Circum</li> </ul>	in headed "Circu b in the form instances": C874 in headed "Circu ses": P8741 in headed "Purp ib in the form instances": C874 in headed "Circu	umstances": C1 Injection 50 n 41 umstances": C1 loses": P14171 Injection 50 n 41 umstances": C1	ng in 0.5  4171 ng in 0.5  4171	5 mL sin	gle use pre-filled syring	e [Maximum		

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				а	Noumed Irbesartan	VO	MP NP			30	5	30	
14]	Schedule 1	, Part 1, entry for Lamivudi	ne with zi	dovud	dine								
	insert in the c	columns in the order indicated, a	and in alph	abetica	al order for the colu	ımn h	eaded "Br	and":					
				а	Lamivudine/Zidovuc ine Viatris 150/300	AL	MP NP	C4454 C4512		120	5	60	D(100)
-	Schedule 1, omit:	, Part 1, entry for Lamotrigi	ine in eac	h of tl	ne forms: Tablet	25 m	ng; Tablet	t 50 mg; Tablet	100 mg; and T	ablet 2	200 mg		
				а	Lamotrigine Sandoz	z SZ	MP NP	C11081		56	5	56	
	omit:			а	Sandoz Metformin	НХ	MP NP			90	5	90	
17]	0.1.1.1.4												
	Schedille 1	Part 1 entry for Methador	10										
_	substitute:	, Part 1, entry for Methador	10										
_	substitute:	, Part 1, entry for Methador Injection containing methadone hydrochloride 10 mg in 1 mL	ne Injection		Physeptone	AS	MP NP	C10745 C10747 C10751 C11696	P10745 P10747 P10751	5	0	5	
_	substitute:	Injection containing methadone			Physeptone	AS	MP NP MP NP		P10751	5 120	0	5	
-	substitute:	Injection containing methadone	Injection	а	Physeptone Aspen Methadone Syrup	AS AS		C10751 C11696 C10745 C10747	P10751		-		PB(100)
_	substitute:	Injection containing methadone hydrochloride 10 mg in 1 mL Oral liquid containing methadone hydrochloride 25 mg per 5 mL in	Injection	а	Aspen Methadone	AS	MP NP	C10751 C11696 C10745 C10747 C10751 C11696	P10751	120	0	5	
_	substitute:	Injection containing methadone hydrochloride 10 mg in 1 mL Oral liquid containing methadone hydrochloride 25 mg per 5 mL in	Injection	-	Aspen Methadone Syrup	AS	MP NP MP NP	C10751 C11696 C10745 C10747 C10751 C11696 C14178	P10751	120 840	0	5 1000	PB(100) PB(100)
_	substitute:	Injection containing methadone hydrochloride 10 mg in 1 mL Oral liquid containing methadone hydrochloride 25 mg per 5 mL in 1 L bottle, 1 mL Oral liquid containing methadone hydrochloride 25 mg per 5 mL in	Injection	-	Aspen Methadone Syrup Biodone Forte Aspen Methadone	AS	MP NP MP NP MP NP	C10751 C11696 C10745 C10747 C10751 C11696 C14178 C14178	P10751 P11696	120 840 840	0 2 2	5 1000 1000	

				Syrup								
			а	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 Mirtazap	oine in the	form 1	Fablet 15 mg								
	insert in the columns in the order indicated	, and in alph	abetica	al order for the col	umn h	eaded "Br	and":					
			а	Blooms The Chemist Mirtazapine	BG	MP NP	C5650		30	5	30	
49]	Schedule 1, Part 1, entry for Mirtazap	oine in the	form T	Fablet 15 mg (or	ally d	isintegra	ting)					
	omit:											
	omit:		а	Mirtazapine Sando ODT 15	z SZ	MP NP	C5650		30	5	30	
50]	omit: Schedule 1, Part 1, entry for Mirtazap	pine in the		ODT 15	z SZ	MP NP	C5650		30	5	30	
50]			form 1	ODT 15					30	5	30	
50]	Schedule 1, Part 1, entry for Mirtazap		form 1	ODT 15	umn h				30 30	5	30 30	
50] 51]	Schedule 1, Part 1, entry for Mirtazap	, and in alph	form 1 abetica a	ODT 15 <b>Tablet 30 mg</b> <i>al order for the col</i> Blooms The Chemist Mirtazapine	umn h BG	eaded "Br MP NP	and": C5650					

		а	Blooms The Chemist Mirtazapine	BG	MP NP	C5650		30	5	30
3]	Schedule 1, Part 1, entry for Mirtazapine in the f	orm	Гablet 45 mg (o	rally c	lisintegra	iting)				
		а	Mirtazapine Sando ODT 45	oz SZ	MP NP	C5650		30	5	30
4]	Schedule 1, Part 1, entry for Nirmatrelvir and rit	onav	r							
	(a) omit from the column headed "Circumstances":	C137	65							
	(b) omit from the column headed "Circumstances":	C138	93							
	(c) <i>insert in numerical order in the column headed</i>	'Circı	umstances": C141	87						
5]	Schedule 1, Part 1, entry for Oxycodone in the f	orm(	Capsule contair	ning o	xycodon	e hydrochloride	10 mg			
-	substitute:		•	•	•	•	-			
	Capsule containing oxycodone Oral hydrochloride 10 mg		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		20	0	20
					PDP	C10766 C10768	P10768	20	0	20
					1 01					
56]	Schedule 1, Part 1, entry for Paroxetine									
56]	Schedule 1, Part 1, entry for Paroxetine insert in the columns in the order indicated, and in alpha	abetic	al order for the co	lumn h		and":				
6]	· · · •	<i>abetic</i> a	<i>al order for the co</i> Noumed Paroxetir		eaded "Br	cand": C4755 C6277 C6636		30	5	30
56]	· · · •	а	Noumed Paroxetir	ne VO	eaded "Br MP NP	C4755 C6277 C6636	) )	30	5	30

	centrate for I.V. Injection mg (as disodium) in		Pemetrexed Ever Pharma	IT	MP	See Note 3	See Note 3	1	D(100)
	centrate for I.V. Injection mg (as disodium) in		Pemetrexed Ever Pharma	IT	MP	See Note 3	See Note 3	1	D(100)
	centrate for I.V. Injection as disodium) in		Pemetrexed Ever Pharma	IT	MP	See Note 3	See Note 3	1	D(100)
58] Schedule 1, Part 1, ent	try for Pravastatin in th	e form T	Tablet containing	g pra	vastatin sodium 80 mg				
<b>(a)</b> <i>omit:</i>									
		а	Pravastatin Sandoz	sz	MP NP	30	5	30	
<b>(b)</b> <i>omit:</i>									

## [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 f	form 1	Fablet 40 mg								
	omit:											
			а	Telmisartan GH	GQ	MP NP			28	5	28	
[61]	Schedule 1,	, Part 1, entry for Tocilizumab										
	substitute:	-										
Tocilizuma	ab	Concentrate for injection 80 mg in Injection 4 mL		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)
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				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	$\begin{array}{c} C8627 \ C8633 \\ C8638 \ C9180 \\ C9380 \ C9386 \\ C9391 \ C9477 \\ C9478 \ C9553 \\ C10560 \ C11689 \\ C11781 \ C12193 \\ C12399 \ C12404 \\ C12405 \ C14056 \\ C14080 \ C14084 \\ C14088 \ C14094 \\ C14103 \ C14104 \\ C14121 \ C14147 \\ C14150 \ C14153 \\ C14166 \ C14174 \\ C14175 \ C14182 \end{array}$	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 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		4	3	4

		MP	C8638 C9180	P8627 P8633 P9380 P9553 P14088 P14174	4	5	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				
		MP		P9180	4	6	4
Injection 162 mg in 0.9 mL single Injection use pre-filled syringe	Actemra Subcutaneous Injection	RO MP		P10560	4	0	4

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

	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				
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*:

C874	6 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).	Compliance with Written Authority Required procedures
		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	

	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 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 demonstrate 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.	
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# (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 conditions for the patient medicine treatment for this	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; 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	
		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.	
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
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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 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 not receive more than 16 weeks of treatment under this restriction. Patient must 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 nakle (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 foreatment 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 tre	
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 med months) Must be treated by a rheumatologist; OR	cine of less than 24 Compliance with Written Authority Required procedures
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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
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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).	Code 12116
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.	

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

C14058		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
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	<ul> <li>20% from baseline;</li> <li>AND either of the following: <ul> <li>(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</li> <li>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</li> <li>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</li> <li>(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).</li> <li>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.</li> <li>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.</li> </ul> </li> <li>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.</li> <li>The authority application must be made in writing and must include:</li> <li>(1) a completed authority prescription form; and</li> <li>(2) a completed authority prescription form; and</li> <li>(2) a completed authority appl</li></ul>	
	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	
C1413	36	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 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	
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	Compliance with Written
		Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)	Authority Required procedures
		Must be treated by a rheumatologist; OR	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.	
		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	

treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.			
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# (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	Compliance with Written Authority Required procedures
		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:	
		<ul> <li>(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</li> <li>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</li> <li>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</li> <li>(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 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</li> </ul>	

	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.	
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#### [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 a	existing text:
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	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 C14074 naloxone	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 Stre	Compliance with Authority Required procedures - Streamlined Authority Code 14074
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### [77] Schedule 4, Part 1, entry for Certolizumab pegol

#### (a) *omit*:

C86	8626	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
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Must be treated by a clinical immunologist with expertise in the management of meumatol arthritis.           Patient must not have recived prior PBS-subsidies of treatment with a biological medicine for this condition; AND           Patient must not have alraidy failed , or ceased to respond to, PBS-subsidised treatment with this drug for this condition; AND           Patient must not have alraidy failed , or ceased to respond to, PBS-subsidised to a treatment for this condition; SMD           Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.           Patient must not receive more than 18 to 20 weeks of treatment in 5 mg per L or either marker reduced by at least 20% from baseline.           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.           (a) are duction in the number of the following active joints, from a least 4, by at least 50%:           (b) elow, wrist, knee and/or nkie (assessed as as wollen and tender); and/or           (ii) elow wrist, knee and/or nkie (assessed as and not inreversible damage such as joint destruction or bony overgrowth).           An application for a patient win has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by veidence of a response to the patient's meson received treatment with this drug was approved under either of the initial 1, initial 2, initial 3, or continuing treatment the application must be accompanied with tha sasesesment of a patient's response is conducted followi	
Patient must have received prior PBS-subsidied treatment with a biological medicine for this condition; AND Patient must not have alied to respond to predivate PBS-subsidied biological medicine treatment for this condition 5 times; AND Patient must not neceive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. 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 number of the following active joints, from at least 50% from baseline, where baseline is at least 20 or the reduction in the number of the following active joints, from at least 4, by at least 50%; (i) elbow, wrist, knee and/or ankie (assessed as swill and tender) and/or (ii) shoulder and/or hig (assessed as swill no passive movement, and restriction of passive movement, where pain and limitation of movement are due to active disease and not intreversible damage such as joint destruction or bony overgrowth). An application for a patient with his drug, within the imferances specified below. Where the most recent course of PBS-subsidised treatment with this drug and who wisks to re-commence therapy with this drug, within the imferances specified below. Where the most recent course of therapy and no iater than 4 weeks from the completion of a patient seponse is conticuted following a minimum of 12 weeks of therapy and no iater 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 asponse from the date of completion of the most recent course of treatment. To demonstrate a treaponse to treatment mething day of this acondition. Where the most recent course of	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
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<ul> <li>condition 5 times; AND</li> <li>Patient must hor receive more than 16 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older.</li> <li>An adequate response to treatment is defined as:</li> <li>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;</li> <li>AND either of the following;</li> <li>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 achive joints; or</li> <li>(b) areduction in the total active (swollen and tender) joint count by at least 50%;</li> <li>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</li> <li>(ii) shoulder and/or hig (assessed as swollen and tender); and/or</li> <li>(ii) shoulder and/or hig (assessed as swollen and tender); and/or</li> <li>(ii) shoulder and/or hig (assessed as swollen and tender); and/or</li> <li>(ii) shoulder and/or hig (assessed as swollen and tender); and/or</li> <li>(iii) shoulder and/or hig (assessed as swollen and tender); and/or</li> <li>(iii) shoulder and/or hig (assessed as swollen and tender); and/or</li> <li>(iii) shoulder and/or hig (assessed as swolles) treatment with this drug and who wishes to re-commence theraps with this drug and who wishes to re-commence theraps, with the discase and his is 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 the most recent course of treatment the application must be accompanied with the assessment of response from the date of completion of the most recent course of treatment thas upontient. This is to ensure continuing of treatment for the set who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.</li> <li>Where the most recent course of treatment t</li></ul>	
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<ul> <li>(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</li> <li>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</li> <li>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</li> <li>(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 inreversible damage such as joint destruction or bory 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, must be accompanied by evidence of a response to the 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.</li> <li>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of treatment.</li> <li>To demonstrate a response to treatment with this drug from the assessment of response 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 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 provided within this timefrom.</li> <li>Where a response assessment is not provided within this drug for this condition.</li> <li>Where a response assessment is not provided within this timefrom the will not be eligible to receiving for permanent with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent with this drug on the w</li></ul>	
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(b) *insert in numerical order after existing text:* 

C14113 P14113 Severe active rheumatoid arthritis Compliance with Wr
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Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24	Authority Required
months).	procedures
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	
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If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive	
In a patient rais to demonstrate a response to treatment with this drug under this restriction tiley will hot 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.	
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#### [78] Schedule 4, Part 1, entry for Choriogonadotropin alfa

#### substitute:

Choriogonadotropin alfa	C14096	Patie Medi Patie Must Must Must Must The	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 an endocrinologist; 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
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	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
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c	C14154	treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Severe active juvenile idiopathic arthritis Continuing treatment	Compliance with Authority Required
		<ul> <li>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</li> <li>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.</li> <li>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy</li> </ul>	
		for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and	
		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	
		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.	
		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	
		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	
		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,	
		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	
		<ul> <li>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</li> <li>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and</li> </ul>	
		<ul> <li>(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</li> <li>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</li> </ul>	
		20% from baseline; AND either of the following:	
		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	
		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.	
		Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older.	
		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	

		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 neponse 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	procedures - Streamlined Authority Code 14154
C'	14155	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

	<ul> <li>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</li> <li>(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).</li> <li>The assessment of response to treatment must be documented in the patient's medical records.</li> <li>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.</li> <li>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.</li> <li>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 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.</li> <li>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug after a minimum of 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.</li> <li>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.</li> </ul>	
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#### [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 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
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#### [82] Schedule 4, Part 1, entry for Fluticasone propionate

### substitute:

	Fluticasone propionate	C14180			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
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#### [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%:	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	
		<ul> <li>(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).</li> <li>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.</li> </ul>	
		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. This 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

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

	C14171	P14171	Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24	Compliance with Written Authority Required procedures
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<ul> <li>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 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.</li> <li>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.</li> <li>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.</li> <li>The authority application must be made in writing and must include:</li> <li>(1) a completed authority prescription form(s); and</li> <li>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</li> </ul>	
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:
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C6480 Opiate dependence
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#### (b) *insert in numerical order after existing text:*

C14178		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	Compliance with Authority Required procedures - Streamlined Authority Code 14178
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#### [85] Schedule 4, Part 1, entry for Nirmatrelvir and ritonavir

#### (a) *omit*:

	C13765			SARS-CoV-2 infection	Compliance with
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Patient must have received a positive polymerase chain reaction (PCR) test result; OR	Authority Required
Patient must have received a positive rapid antigen test (RAT) result; AND	procedures -
Patient must have at least one sign or symptom attributable to COVID-19; AND	Streamlined Authority
Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND	Code 13765
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,	
<ol><li>Neurological conditions, including stroke and dementia and demyelinating conditions,</li></ol>	
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.	

# **(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
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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	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	Compliance with Authority Required procedures - Streamlined Authority Code 14187
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<ul> <li>8. Renal impairment (eGFR less than 60mL/min)</li> <li>9. Cirrhosis</li> <li>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</li> <li>11. Past COVID-19 infection episode resulting in hospitalisation.</li> <li>Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.</li> <li>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.</li> <li>Access to this drug through this restriction is permitted irrespective of vaccination status.</li> <li>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.</li> <li>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.</li> </ul>
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	<ul> <li>Severe active rheumatoid arthritis Continuing treatment</li> <li>Must be treated by a rheumatologist; OR</li> <li>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</li> <li>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</li> <li>Patient must have demonstrated an adequate response to treatment with this drug; AND</li> <li>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.</li> <li>Patient must be aged 18 years or older.</li> <li>An adequate response to treatment is defined as:</li> <li>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;</li> <li>AND either of the following:</li> <li>(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</li> <li>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</li> </ul>	Compliance with Written Authority Required procedures

C8638	P8638	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	Compliance with Authority Required procedures
		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.	
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

		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; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of 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

		<ul> <li>(1) completed authority prescription form(s); and</li> <li>(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>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.</li> </ul>	
C9477	P9477	<ul> <li>Severe active juvenile idiopathic arthritis</li> <li>Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply</li> <li>Must be treated by a paediatric rheumatologist; OR</li> <li>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</li> <li>Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 16 or 24 weeks treatment; OR</li> <li>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</li> <li>Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 or 24 weeks treatment; OR</li> <li>Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 or 24 weeks treatment; OR</li> <li>Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 or 24 weeks treatment; OR</li> <li>Patient must provide no more than 12 months) restriction to complete 16 or 24 weeks treatment; AND</li> <li>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions for patients under 30 kg.</li> </ul>	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 number of the following active joints, from at least 4, by at least 50%. (i) elbow, wrist, knee and/or ankle (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include: (i) 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 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 and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. Where the response assessment is not submitted within this imframe, the patient will be deemed to have failed to respond to treatment. Where the response assessment is not considered as a treat	
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	
		<ul> <li>(c) a reduction in the number of the following active joints, from at least 50% information baseline, or (i) a reduction in the number of the following active joints, from at least 4, by at least 50%:</li> <li>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</li> <li>(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).</li> <li>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</li> </ul>	
		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-	
		It a patient rails 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	
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		<ul> <li>weight being administered a subcutaneous form of this biological medicine</li> <li>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</li> <li>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</li> <li>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</li> <li>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</li> <li>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</li> <li>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</li> </ul>	
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 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 previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must nave 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 must have a nelevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a nelevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a circacitve protein (CRP) level greater than 15 mg per L; AND The condition must have a circacitve protein (CRP) level greater than 15 mg per L; 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 high	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 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 20 mg weekly and one of which must be: (ii) hydroxychloroquine, in dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 20 mg weekly dose, must include at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 20 mg weekly dose, must include at a dose of at least 10 mg daily; or (iii) bydroxychloroquine at a dose of at least 20 mg weekly dose, must include at least 5 months continuous 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 20 mg daily; and/or (iii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 20 mg daily; and/or (iii) leflunomide at a dose of at least 20 mg daily; and/or (iii) leflunomide, iii bat a dose 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 patient must have a contraindicated accord	

012102		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 doced 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. Where the baseline is determined at unmber of angor 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	
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 Writter 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

		<ul> <li>this criterion cannot be satisfied.</li> <li>The authority application must be made in writing and must include: <ul> <li>(1) completed authority prescription form(s); and</li> <li>(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.</li> <li>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.</li> <li>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.</li> <li>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.</li> </ul> </li> </ul>	
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 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 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 to the alternative biological medicine 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; or (b) a reduction in the active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joints; or (c) a reduction in the active (swollen and tender) joints; or (b) a redu	Compliance with Written Authority Required procedures

		<ul> <li>pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</li> <li>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.</li> <li>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.</li> <li>If a patient 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 failure.</li> <li>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.</li> <li>If a patient fails to respond to PBS-subsidised biological medicine therapy in this treatment cycle.</li> </ul>	
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 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 to the alternative biological medicine as the shortage has been resolved. An ade	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%:	
	<ul> <li>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</li> <li>(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</li> </ul>	
	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 receive further 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	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;	Compliance with Written Authority Required procedures
	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	

ГТ	I I		,
		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 r	
C14056		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 diseases 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 with this drug for this condition. Where a response assessment is not provided within this itmeframe, 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 autho	
		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	<ul> <li>Systemic juvenile idiopathic arthritis</li> <li>Initial treatment - Initial 1 (new patient weighing at least 30 kg)</li> <li>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</li> <li>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</li> <li>Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR</li> <li>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</li> <li>Patient must not receive more than 16 weeks of treatment under this restriction.</li> <li>Patient must be under 18 years of age.</li> <li>Must be treated by a rheumatologist; OR</li> </ul>	Compliance with Authority Required procedures

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

	14084	P14084	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 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	
C1	14084	P14084	<ul> <li>Systemic juvenile idiopathic arthritis</li> <li>Continuing treatment in a patient weighing less than 30 kg</li> <li>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</li> <li>Patient must have demonstrated an adequate response to treatment with this drug; AND</li> <li>Patient must not receive more than 24 weeks of treatment under this restriction.</li> <li>Must be treated by a rheumatologist; OR</li> <li>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</li> <li>An adequate response to treatment is defined as:</li> <li>(a) in a patient with polyarticular course disease:</li> <li>(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</li> </ul>	Compliance with Authority Required procedures - Streamlined Authority Code 14084

			<ul> <li>(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%: <ul> <li>elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</li> <li>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).</li> <li>(b) in a patient with refractory systemic symptoms:</li> <li>(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or</li> <li>(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or</li> <li>(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.</li> <li>The assessment of response to treatment must be documented in the patient's medical records.</li> <li>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.</li> <li>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 will be deemed to have failed that most recent course 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 with these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</li> </ul> </li> <li>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 to treatme</li></ul>	
c	214088	P14088	<ul> <li>Systemic juvenile idiopathic arthritis</li> <li>Continuing treatment in a patient weighing at least 30 kg</li> <li>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</li> <li>Patient must have demonstrated an adequate response to treatment with this drug; AND</li> <li>Patient must not receive more than 24 weeks of treatment under this restriction.</li> <li>Must be treated by a rheumatologist; OR</li> <li>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</li> <li>An adequate response to treatment is defined as:</li> <li>(a) in a patient with polyarticular course disease:</li> <li>(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</li> <li>(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:</li> <li>elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</li> <li>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).</li> </ul>	Compliance with Authority Required procedures - Streamlined Authority Code 14088

			<ul> <li>(b) in a patient with refractory systemic symptoms:</li> <li>(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or</li> <li>(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or</li> <li>(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.</li> <li>The assessment of response to treatment must be documented in the patient's medical records.</li> <li>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.</li> <li>The following reports must be documented in the patient's medical records where appropriate:</li> </ul>	
			<ul> <li>(a) baseline and current pathology reports detailing C-reactive protein (CRP) levels; and</li> <li>(b) baseline and current pathology reports detailing platelet count.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-</li> </ul>	
C	C14093	P14093	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. 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:	Compliance with Authority Required procedures - Streamlined Authority Code 14093
			<ul> <li>(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</li> <li>(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:</li> <li>elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</li> <li>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).</li> <li>(b) in a patient with refractory systemic symptoms:</li> <li>(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or</li> </ul>	

		<ul> <li>(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or</li> <li>(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.</li> <li>The assessment of response to treatment must be documented in the patient's medical records.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>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 ad</li></ul>	
		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		Compliance with Authority Required procedures

			<ul> <li>pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</li> <li>The assessment of response to prior treatment must be documented in the patient's medical records.</li> <li>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:</li> <li>(a) an active joint count of at least 2 active joints; and</li> <li>(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or</li> <li>(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).</li> <li>The assessment of response to prior treatment must be documented in the patient's medical records.</li> <li>The baseline measurements of joint count, fever and/or CRP level and platelet count have the commencement of treatment with each initial treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</li> <li>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.</li> <li>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.</li> <li>Toxicity due to methotrexate is defined as evidence of hepatotxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.</li> <li>If intolerance to treatment develops during the relevant predical records.</li> <li>If notlerance to treatm</li></ul>	
C14	4103 P14	4103	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

		<ul> <li>alone or in combination with corticosteroids, for a minimum of 3 months.</li> <li>Patient must be under 18 years of age.</li> <li>Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or conting 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.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:</li> <li>(a) an active joint count of at least 20 active (swollen and tender); and/or</li> <li>(i) elbow, wrist, knee and/or nakle (assessed as svallen and tender); and/or</li> <li>(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 no tirreversible damage such as joint destruction or bony overgrowth).</li> <li>The assessment of response to prior treatment must be documented in the patient's medical records.</li> <li>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records.</li> <li>(a) the date of a</li></ul>	
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

I4121 P14121	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 nakle (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 covergrowth). 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 course. Beatient 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 treatment cycle after a break of more t	Compliance with Authority Required procedures
	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.	

		<ul> <li>(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:</li> <li>(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 systemic below.</li> <li>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 cycle.</li> <li>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.</li> </ul>	
C14147	P14147		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 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 swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as an 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 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 will be deemed to have failed that most recent course of treatment 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 the last continuing prescription. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to record course of PBS-subsidised biological medicine treatment for this condition who wishes to record course of PBS-subsidised biological medicine treatment specified below. The assessment of the patient's response to the most recent course of othe attreatment course. If the response assessment is not co	
			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.	
C14	4164	P14164	Must be treated by a rheumatologist; OR	Compliance with Authority Required procedures - Streamlined Authority Code 14164

C14166 P	214166	(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 of this condition within this treatment cycle. Serious adverse reaction of 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. Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change	Compliance with Authority Required procedures
C14166 P	214166	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. 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	Authority Required
		during the current treatment cycle.	
		An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to	

		<ul> <li>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.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>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.</li> </ul>	
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 a dat performed 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 temporal artery biopsy revealing features of giant cell arteritis at diagnosis; AND 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 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 tendemess, temporal artery tendemess 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 t	Compliance with Written Authority Required procedures

	<ul> <li>than 24.5 mg/L at diagnosis.</li> <li>All reports must be documented in the patient's medical records.</li> <li>If the application is submitted through HPOS form upload or mail, it must include:</li> <li>(i) A completed authority prescription form; and</li> <li>(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).</li> </ul>	
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 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 as wollen and tender); and/or (i) a reduction in the creative protein (CRP) level and platelet count by at least 30% from baseline; and/or (ii) a celuction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) 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 dreating C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dreated the date of 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 for this condition who wishes to retrial or recommence therapy with this drug, must be accompanied by detalis of the e	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	Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority Code 14179

C14182	P14182	Systemic juvenile idiopathic arthritis	Compliance with
		Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months in a patient weighing	Authority Required
		less than 30 kg) Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months; AND	procedures
		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.	

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

(a) *omit*:

C8750	P8750	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	Authority Required
		months) Must be treated by a rheumatologist; OR	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.	
		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 of	der after existing text:	
(b) insert in numerical of 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	Compliance with Writt Authority Required procedures

biological medicine.			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.	
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# [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) ellow wrist knee and/or ankle (assessed as swollen and tender); and/or	Compliance with Written Authority Required procedures
		<ul> <li>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</li> <li>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</li> <li>(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 group and who wishes to re-commence therapy mith this drug, conducted within the timeframes specified below.</li> <li>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</li> </ul>	
		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.	
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(b) *insert in numerical order after existing text:* 

C14170	P14170	<ul> <li>Severe active rheumatoid arthritis</li> <li>Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)</li> <li>Must be treated by a rheumatologist; OR</li> <li>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</li> <li>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR</li> <li>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</li> <li>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</li> <li>Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND</li> <li>Patient must not receive more than 16 weeks of treatment under this restriction.</li> <li>Patient must not received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.</li> <li>An adequate response to treatment is defined as:</li> <li>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;</li> <li>AND either of the following:</li> <li>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20</li> </ul>	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 path subsidised treatment with this drug, conducted within the timeframes specified belod To demonstrate a response to treatment the application must be accompanied with following a minimum of 12 weeks of therapy and no later than 4 weeks from cessa medicine. It is recommended that an application for the continuing treatment be su date of completion of the most recent course of treatment. This is to ensure treatm continuing restriction. Where a response assessment is not conducted within the required timeframe, the respond to treatment with this drug, unless the patient has experienced a serious a the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than determined according to the reduction in the total number of major join 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 Inform If a patient fails to demonstrate a response to a course of rituximab must have a 1 treatment-free period of at least 22 weeks, immediately following the second infusi biological medicine.	low. th the assessment of response, conducted ation of the most recent course of biological ubmitted no later than 4 weeks from the nent continuity for those who meet the e patient will be deemed to have failed to adverse reaction of a severity resulting in n 20 active joints), response must be the baseline is determined on total number nts. If only an ESR or CRP level is provided mation Form. restriction they will not be eligible to receive PBS-subsidised biological therapy
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# [89] Schedule 4, Part 1, entry for Zanubrutinib

omit:

C13020	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 Patient must not have developed disease progression while receiving non-PBS-subsidised treatment with this drug for this	Compliance with Authority Required procedures
	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	

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:

GF	RP-27087	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Yuflyma
		Injection 40 mg in 0.8 mL pre-filled syringe		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:

GRI	RP-27089 I	njection 40 mg in 0.4 mL pre-filled syringe	Injection	Yuflyma
	I	njection 40 mg in 0.8 mL pre-filled syringe		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