

PB 11 of 2023

# National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 2)

National Health Act 1953

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

Dated 27 February 2023

#### NIKOLAI TSYGANOV

Assistant Secretary
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. 2).
- (2) This Instrument may also be cited as PB 11 of 2023.

#### 2 Commencement

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

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

Note: This table relates only to the provisions of this instrument as originally made.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

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

#### 3 Authority

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

#### 4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

#### **Schedule 1—Amendments**

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

#### [1] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen

substitute:

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 C11777 C11720 C11759 C11761 C11767 C11769 C11772 C11810 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12157 C12158 C12174 C12175 C12176 C12189 C12190 C12194 C12212 C12214 C12228 C12234 C12240 C12275 C12273 C12275 C12315 C12336 C13550 C13556	P11713	2	0	2	

C13599 C13602 C13608 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694  Yuflyma  EW MP  C8638 C9064 C13681 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11605 C11606 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11769 C11769 C11772 C11810 C11805 C11805 C11805 C11806
C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694  Yuflyma  EW MP  C8638 C9064 P11713 2 0 2 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 C11770 C11761 C11770 C11769 C11772 C11810
C13699 C13612 C13648 C13650 C13681 C13682 C13683 C13694  Yuflyma  EW MP  C8638 C9064 P11713 2 0 2 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11604 C11635 C11704 C11635 C11704 C11713 C11715 C11718 C11717 C11718 C11717 C11718 C11720 C11759 C11760 C11760 C11760 C11767 C11769 C11777 C11810
C13648 C13650 C13681 C13682 C13683 C13694  Yuflyma EW MP C8638 C9064 P11713 2 0 2 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 C11769 C11772 C11769
C13681 C13682 C13683 C13694  Yuflyma  EW MP  C8638 C9064 P11713 P1713 P1715 P1
C13683 C13694  Yuflyma EW MP C8638 C9064 P11713 2 0 2 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11772 C11810
Yuflyma EW MP C8638 C9064 P11713 2 0 2 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11777 C11718 C11720 C11759 C11761 C11772 C11810
C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11772 C11810
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Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11777 C11720 C11759 C11761 C11772 C11810 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11906 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12189 C12101 C12222 C12123 C12214 C12228 C12234 C12240 C12275 C12176 C12189 C12107 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13608 C13607 C13609 C13612 C13648 C13650 C13683 C13684	P11852 P11854 P11855 P12098 P12101 P12147	2	2	2
Yuflyma	EW	MP	C8638 C9064 C9386 C9715 C11107 C11523	P9715 P11709 P11715 P11716 P11759 P11761	2	2	2

C11524 C11529 P11854 P11855 P12098 C11605 C11606 P12101 P12147 C1631 C1163 C11605 C11606 P12101 P12147 C1631 C11634 P13602 P13609 C11635 C11704 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11718 C11720 C11767 C11769 C11761 C11767 C11769 C11771 C11852 C11853 C11854 C11855 C11864 C11855 C11864 C11855 C11865 C11867 C11790 C1170 C12122 C12123 C12131 C12147 C12136 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12177 C12186 C12177 C12186 C12177 C12176 C12176 C12176 C12176 C12177
C11579 C11604 C11605 C11606 C11605 C11606 C11631 C11634 C11631 C11634 C11635 C11704 C11635 C11704 C11709 C11711 C11713 C11715 C11714 C11720 C11718 C11720 C11759 C11761 C11772 C11810 C11852 C11853 C11854 C11855 C11861 C11865 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12148 C12155 C12186 C12157 C12158 C12157
C11605 C11606 P12101 P12147 C11631 C11634 P13602 P13609 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11718 C11720 C11759 C11761 C11772 C11810 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12165 C12157 C12156 C12157
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C13694
Humira VE MP C8638 C9064 P8638 P9064 2 3 2
C9386 C9715 P9386 P11810
C11107 C11704 P11861 P12131
C11709 C11711 P12174 P12194
C11713 C11715 P13550 P13599

Yuflyma	EW MP	C11716 C11717 C11720 C11759 C11761 C11767 C11769 C117767 C11810 C11852 C11853 C11854 C11855 C11861 C11865 C11865 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 C13556 C13559 C13602 C13606 C13607 C13608 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634	P8638 P9064 P9386 P11810 P11861 P12131 P12174 P12194 P13550 P13599 P13606 P13648 P13650 P13681	2	3	2
		C11579 C11604 C11605 C11606	P13550 P13599 P13606 P13648 P13650 P13681			

		C11767 C11769	
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		C11861 C11865	
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		C11906 C11966	
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		C12122 C12123	
		C12131 C12147	
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		C13612 C13648	
		C13650 C13681	
		C13682 C13683	
		C13694	
Humira	VE MP	C8638 C9064 P11107 P12155 2	4 2
		C9386 C9715 P12212 P13556	
		C11107 C11704 P13607 P13612	
		C11709 C11711 P13683	
		C11713 C11715	
		C11716 C11717	
		C11720 C11759	
		C11761 C11767	
		C11769 C11772	
		C11709 C11772 C11810 C11852	
		C11853 C11854	
		U 1 1000 U 1 1004	
		C11855 C11861	
		C11855 C11861 C11865 C11867	
		C11855 C11861 C11865 C11867 C11903 C11906	
		C11855 C11861 C11865 C11867	

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Yuflyma	EW MP		2	4	2	

			C12148 C12155				
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			C13602 C13606				
			C13607 C13609				
			C13612 C13648				
			C13650 C13681				
			C13682 C13683				
			C13694				
Humira	VE	MD	C8638 C9064	P11704 P11711	2	5	2
Tiullilla	٧L	IVII	C9386 C9715	P11717 P11720	2	3	2
				P11767 P11769			
				P11772 P11853			
			C11713 C11715				
				P11903 P11906			
				P11966 P12122			
				P12123 P12148			
				P12156 P12157			
				P12158 P12175			
				P12176 P12189			
				P12190 P12214			
				P12228 P12234			
			C11903 C11906				
			C11966 C12098				
			C12101 C12122				
			C12123 C12131				
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			C121/4 C121/5				
			C12174 C12175 C12176 C12189				
			C12176 C12189				
			C12176 C12189 C12190 C12194				

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Yuflyma EW MP	C8638 C9064 P11523 P11524 2 5 2  C9386 C9715 P11579 P11604  C11107 C11523 P11605 P11606  C11524 C11529 P11631 P11634  C11579 C11604 P11635 P11704  C11605 C11606 P11711 P11717  C11631 C11634 P11769 P11769  C11709 C11711 P11772 P11853  C11713 C11715 P11865 P11867  C11716 C11717 P11903 P11906  C11718 C11720 P11966 P12122  C11759 C11761 P12123 P12148  C11767 C11769 P12158 P12157  C11852 C11853 P12176 P12189  C11854 C11855 P12190 P12214  C11867 C11906  C12098 C12101  C12122 C12123  C12144 C12155  C12158 C12174  C12175 C12176  C12199 C12190  C12194 C12212  C1224 C12228  C12234 C12240  C12272 C12273  C12275 C12315

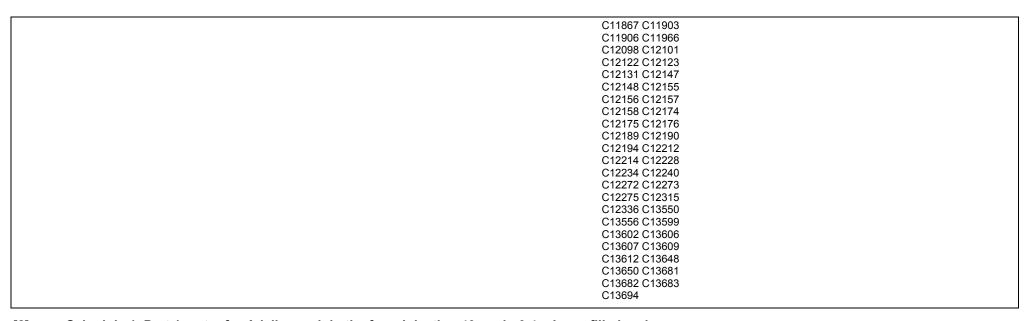
			C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683					
		MD	C13694		2	E	2	C(100)
		MP	C11526 C12116	D40070	2	5	2	C(100)
Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11760 C11775 C11769 C11772 C11810 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11906 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12148 C12157 C12189 C12101 C12122 C12233 C12214 C12228 C12214 C12228 C12234 C12228 C12234 C12240 C12272 C12273 C12275 C12315 C12336 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650	P12273	4	2	2	

			C13681 C13682				
			C13683 C13694				
Yuflyma	EW N	MP	C8638 C9064	P12273	4	2	2
, ,			C9386 C9715				
			C11107 C11523				
			C11524 C11529				
			C11579 C11604				
			C11605 C11606				
			C11631 C11634				
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			C13694				

Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11777 C11720 C11759 C11761 C11767 C11769 C11772 C11810 C11852 C11853 C11854 C11855 C11861 C11865 C11861 C11865 C11865 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 C13608 C13612 C13648 C13650 C13681 C13682 C13681 C13682 C13683 C13694	P12272 P12315	4	5	2
Yuflyma	EW	MP	C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704	P11529 P12272 P12315	4	5	2

		C11709 C11711
		C11713 C11715
		C11716 C11717
		C11718 C11770
		C11718 C11720 C11759 C11761
		C11767 C11769
		C11772 C11810
		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
I to see to a	\/E	00000 00004
Humira	VE MP	
		C9386 C9715 P11715 P11716
		C11107 C11704 P11759 P11761
		C11709 C11711 P11852 P11854
		C11713 C11715 P11855 P12098
		C11716 C11717 P12101 P12147
		C11720 C11759 P12275 P12336
		C11761 C11767 P13602 P13609
		C11769 C11772
		C11810 C11852
		G11010 G11032

			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				
V.	G 5144		00000 00004	D0745 D44700	•	•	
Yu	uflyma EW	MP	C8638 C9064	P9715 P11709	6	0	2
			C9386 C9715	P11715 P11716			
			C11107 C11523	P11759 P11761			
			C11524 C11529	P11852 P11854			
			C11579 C11604	P11855 P12098			
			C11605 C11606				
			C11631 C11634				
			C11635 C11704				
				F 13002 F 13009			
			C11709 C11711				
			C11713 C11715				
			C11716 C11717				
			C11718 C11720				
			C11759 C11761				
			C11767 C11769				
			C11772 C11810				
			C11852 C11853				
			C11854 C11855				
			C11861 C11865				



## [2] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe substitute:

Injection 40 mg in 0.4 mL pre- filled syringe	Injection	Humira	VE	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
		Yuflyma	EW	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	C(100)
		Humira	VE	MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11720 C11759 C11761 C11767 C11769 C11772 C11810 C11852	P11713	2	0	2	

		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				
Yuflyma	EW 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				
		C11810 C11852				
		C11853 C11854				
		C11855 C11861				
		C11865 C11867				
		C11903 C11906 C11966 C12098				
		C11066 C12000				

		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 C13682 C13683 C13694				
Humira	VE MP	C11713 C11715 C11716 C11717	P11852 P11854 P11855 P12098	2	2	2

		C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694				
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 C11767 C11767 C11769 C11772 C11810 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12131 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12175 C12176 C12194 C12228 C12234 C12228 C12234 C12240 C13550 C13556 C13599 C13602 C13606 C13607 C13608	P11852 P11854 P11855 P12098 P12101 P12147	2	2	2

			C13650 C13681				
			C13682 C13683				
			C13694				
Humira	VE	MP	C8638 C9064	P8638 P9064	2	3	2
			C9386 C9715	P9386 P11810			
			C11107 C11704				
			C11709 C11711				
			C11713 C11715				
			C11716 C11717 C11720 C11759				
			C11720 C11739				
			C11769 C11772	1 100021 10001			
			C11810 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				
			C12170 C12103				
			C12212 C12214				
			C12228 C12234				
			C12240 C13550				
			C13556 C13599				
			C13602 C13606 C13607 C13609				
			C13612 C13648				
			C13650 C13681				
			C13682 C13683				
			C13694				
V 6			00000 0000:	D0000 D000 :		•	
Yuflyma	EW	MP	C8638 C9064	P8638 P9064	2	3	2
			C9386 C9715 C11107 C11523	P9386 P11810 P11861 P12131			
			C11107 C11523				
			C11604 C11605				
			C11606 C11631				

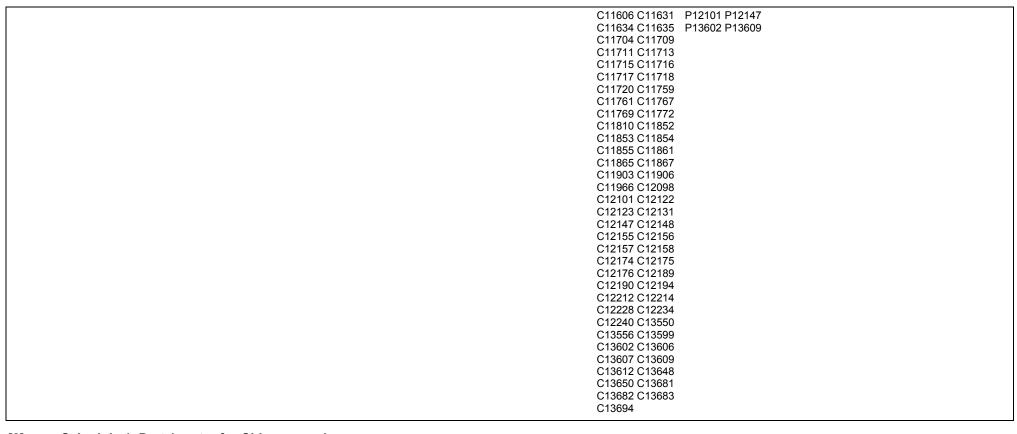
		C11634 C11635	P13650 P13681		
		C11704 C11709			
		C11711 C11713			
		C11715 C11716			
		C11717 C11718			
		C11720 C11759			
		C11761 C11767			
		C11769 C11772			
		C11810 C11852			
		C11853 C11854			
		C11855 C11861			
		C11865 C11867			
		C11903 C11906			
		C11966 C12098			
		C12101 C12122			
		C12123 C12131			
		C12147 C12148			
		C12147 C12146 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			
			D4440= D404== 0		
Humira	VE MP	C8638 C9064	P11107 P12155 2	4	2
		C9386 C9715	P12212 P13556		
		C11107 C11704			
		C11709 C11711	P13683		
		C11713 C11715			
		C11716 C11717			
		C11720 C11759			
		C11761 C11767			
		C11761 C11767 C11769 C11772			
		C11810 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					
Yuflyma	EW MP	C13694	P11107 P12155	2	4	2	
Yuflyma	EW MP		P11107 P12155 P12212 P13556	2	4	2	
Yuflyma	EW MP	C13694 C8638 C9064 C9386 C9715	P12212 P13556	2	4	2	
Yuflyma	EW MP	C13694 C8638 C9064 C9386 C9715 C11107 C11523	P12212 P13556 P13607 P13612	2	4	2	
Yuflyma	EW MP	C13694  C8638 C9064  C9386 C9715  C11107 C11523  C11524 C11579	P12212 P13556 P13607 P13612	2	4	2	
Yuflyma	EW MP	C13694  C8638 C9064  C9386 C9715  C11107 C11523  C11524 C11579  C11604 C11605	P12212 P13556 P13607 P13612	2	4	2	
Yuflyma	EW MP	C13694  C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631	P12212 P13556 P13607 P13612	2	4	2	
Yuflyma	EW MP	C13694  C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635	P12212 P13556 P13607 P13612	2	4	2	
Yuflyma	EW MP	C13694  C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709	P12212 P13556 P13607 P13612	2	4	2	
Yuflyma	EW MP	C13694  C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713	P12212 P13556 P13607 P13612	2	4	2	
Yuflyma	EW MP	C13694  C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716	P12212 P13556 P13607 P13612	2	4	2	
Yuflyma	EW MP	C13694  C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718	P12212 P13556 P13607 P13612	2	4	2	
Yuflyma	EW MP	C13694  C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11606 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759	P12212 P13556 P13607 P13612	2	4	2	
Yuflyma	EW MP	C13694  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	P12212 P13556 P13607 P13612	2	4	2	
Yuflyma	EW MP	C13694  C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11605 C11604 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11776 C11769 C11772	P12212 P13556 P13607 P13612	2	4	2	
Yuflyma	EW MP	C13694  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 C11777 C11810 C11852	P12212 P13556 P13607 P13612	2	4	2	
Yuflyma	EW MP	C13694  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 C11772 C11810 C11852 C11853 C11854	P12212 P13556 P13607 P13612	2	4	2	
Yuflyma	EW MP	C13694  C8638 C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11631 C11634 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11720 C11759 C11761 C11776 C11769 C11772 C11810 C11852 C11853 C11854 C11855 C11861	P12212 P13556 P13607 P13612	2	4	2	
Yuflyma	EW MP	C13694  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 C11772 C11810 C11852 C11853 C11854 C11865 C11861	P12212 P13556 P13607 P13612	2	4	2	
Yuflyma	EW MP	C13694  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 C11763 C11767 C11763 C11767 C11765 C11767 C11769 C117767 C11810 C11852 C11853 C11854 C11865 C11867 C11903 C11906	P12212 P13556 P13607 P13612	2	4	2	
Yuflyma	EW MP	C13694  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 C11775 C11810 C11852 C11853 C11854 C11865 C11867 C11903 C11906 C11966 C12098	P12212 P13556 P13607 P13612	2	4	2	
Yuflyma	EW MP	C13694  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 C11763 C11767 C11763 C11767 C11765 C11767 C11769 C117767 C11810 C11852 C11853 C11854 C11865 C11867 C11903 C11906	P12212 P13556 P13607 P13612	2	4	2	

		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 C13683 C13682 C13683 C13694				
Humira	VE MP	C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11777 C11720 C11759 C11761 C11767 C11769 C11772 C11810 C11852 C11853 C11864 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	P11772 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12175 P12176 P12189 P12190 P12214 P12228 P12234	2	5	2

		C13556 C13599 C13602 C13606 C13607 C13609 C13612 C13648 C13650 C13681 C13682 C13683 C13694				
Yuflyma	EW MP		P11631 P11634 P11635 P11704 P11711 P11717 P11718 P11720 P11767 P11769 P11772 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12175 P12176 P12189 P12190 P12214 P12228 P12234	2	5	2

C13682 C13683 C13694  C11526 C12116  C8638 C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11709 C11711 C11713 C11715 C11716 C11717 C11720 C11759 C11761 C11767 C11769 C11772 C11810 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906	6 1 4 8 7	2 2	C(100)
C8638 C9064 P9715 P11709 C9386 C9715 P11715 P11716 C11107 C11704 P11759 P11761 C11709 C11771 P11852 P11854 C11716 C11717 P12101 P12147 C11760 C11767 C11769 C11772 C11810 C11852 C11853 C11854 C11865 C11861 C11865 C11867	6 0 6 1 4 8 7		C(100)
C9386 C9715 P11715 P11716 C11107 C11704 P11759 P11761 C11709 C11711 P11852 P11854 P1761 C11761 C11769 C11762 C11810 C11855 C11853 C11854 C11865 C11867	6 1 4 8 7	2	
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			
	6	2	
	213556 C13599 213602 C13606 213607 C13609 213612 C13648 213650 C13681 213682 C13683 213694 28638 C9064 P9715 P11709 29386 C9715 P11715 P1171	213556 C13599 213602 C13606 213607 C13609 213612 C13648 213650 C13681 213682 C13683 213694 28638 C9064 P9715 P11709 6 0	213556 C13599 213602 C13606 213607 C13609 213612 C13648 213650 C13681 213682 C13683 213694 28638 C9064 P9715 P11709 6 0 2 29386 C9715 P11715 P11716 211107 C11523 P11759 P11761 211524 C11579 P11852 P11854



#### [3] Schedule 1, Part 1, entry for Chlorpromazine

omit:

Tablet containing chlorpromazine Oral Largactil SW MP NP 100 5 100 hydrochloride 10 mg

## [4] Schedule 1, Part 1, entry for Cinacalcet in the form Tablet 30 mg (as hydrochloride) [Maximum Quantity: 28; Number of Repeats: 5] insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 2)

	а	Cinacalcet Viatris	AL	MP NP	C10068	28	5	28	
5]	Schedule 1, Part 1, entry for Cinacalcet in the form T	ablet 30 mg (as	hydro	chloride	e) [Maximum Quantity:	56; Number of	Repeats:	5]	
	insert in the columns in the order indicated, and in alphabetic	al order for the co	lumn h	eaded "Bi	rand":				
	а	Cinacalcet Viatris	AL	MP	C10063 C10067 C10073	56	5	28	C(100)
6]	Schedule 1, Part 1, entry for Clopidogrel in the form	Tablet 75 mg (as	s hydr	rogen su	Ifate)				
	omit:	Blooms the Chemi	ist IB	MP NP		28	5	28	
]	Schedule 1, Part 1, entry for Epirubicin in the form So	olution for injec	tion c	ontainin	g epirubicin hydrochlo	oride 200 mg in	100 mL		
]		olution for injec		ontainin MP	g epirubicin hydrochlo		100 mL  See Note 3	1	D(100)
		Epirube	ТВ	MP		See Note	e See Note 3		D(100)
	omit:  Schedule 1, Part 1, entry for Ipilimumab in each of th	Epirube e forms: Injectio	ТВ	MP		See Note	e See Note 3		D(100)
	Schedule 1, Part 1, entry for Ipilimumab in each of the concentrate for I.V. infusion 200 mg in 40 mL	Epirube e forms: Injection	TB On COI	MP		See Note	e See Note 3		D(100)
3]	Schedule 1, Part 1, entry for Ipilimumab in each of th concentrate for I.V. infusion 200 mg in 40 mL  (a) omit from the column headed "Circumstances": C101	Epirube e forms: Injection	TB On COI	MP		See Note	e See Note 3		D(100)
3]	Schedule 1, Part 1, entry for Ipilimumab in each of the concentrate for I.V. infusion 200 mg in 40 mL  (a) omit from the column headed "Circumstances": C104  (b) insert in numerical order in the column headed "Circumstances"	Epirube  e forms: Injection  122  umstances": C138	TB on coi	MP ncentrate	e for I.V. infusion 50 m	See Note	e See Note 3		D(100)
7] 3] 9] 10]	Schedule 1, Part 1, entry for Ipilimumab in each of the concentrate for I.V. infusion 200 mg in 40 mL  (a) omit from the column headed "Circumstances": C104  (b) insert in numerical order in the column headed "Circumstances": Schedule 1, Part 1, omit entry for Losartan	Epirube  e forms: Injection  122  umstances": C138	TB on cor	MP ncentrate	e for I.V. infusion 50 mg	See Note	e See Note 3		D(100)

concentrate for I.V. infusion 100 mg in 10 mL

(a)

omit from the column headed "Circumstances": C9214

	(b) omit from the column headed "Circumstan	nces": C101	95					
	(c) insert in numerical order in the column hea	eaded "Circui	mstances": C1	3839 C13852 C1	3853 C13863			
2]	Schedule 1, Part 1, entry for Olmesartan wi 20 mg with amlodipine 5 mg (as besilate) a	-	•		in the form Tablet	containing olmes	artan m	edoxomi
	insert in the columns in the order indicated, and in	n alphabetica	l order for the c	column headed "Bi	and":			
		а	Olamlo HCT 20/5/12.5	AL MP NP	C4311	30	5	30
]	Schedule 1, Part 1, entry for Olmesartan wi 40 mg with amlodipine 5 mg (as besilate) a	-	-		in the form Tablet	containing olmes	artan m	edoxomi
	insert in the columns in the order indicated, and in	n alphabetica	ıl order for the c	column headed "Bi	and":			
							_	00
		а	Olamlo HCT 40/5/12.5	AL MP NP	C4311	30	5	30
1]	Schedule 1, Part 1, entry for Olmesartan wi 40 mg with amlodipine 5 mg (as besilate) a	ith amlodip	40/5/12.5 Dine and hydro	ochlorothiazide				
]		ith amlodip	40/5/12.5 bine and hydro hlorothiazide	ochlorothiazide 25 mg	in the form Tablet			
]	40 mg with amlodipine 5 mg (as besilate) a	ith amlodip	40/5/12.5 bine and hydro hlorothiazide	ochlorothiazide 25 mg	in the form Tablet			
4] 5]	40 mg with amlodipine 5 mg (as besilate) a	ith amlodip and hydrocl an alphabetica a	oine and hydrohlorothiazide order for the cooling HCT 40/5/25	ochlorothiazide 25 mg column headed "Bi AL MP NP	in the form Tablet or and": C4311	containing olmes	artan m	edoxomi 30
	40 mg with amlodipine 5 mg (as besilate) a insert in the columns in the order indicated, and in Schedule 1, Part 1, entry for Olmesartan with the schedule 1, Part 1, entry for Olmesartan with the schedule 2.	ith amlodip and hydrocl a alphabetica a ith amlodip and hydroc	oine and hydrohlorothiazide al order for the of Olamlo HCT 40/5/25 oine and hydrohlorothiazide	ochlorothiazide 25 mg column headed "Bi AL MP NP ochlorothiazide e 12.5 mg	in the form Tablet of the form T	containing olmes	artan m	edoxomi 30

			а	Olamlo HCT 40/10/25	AL	MP NP	C4311		30	5	30	
7]	Schedule 1, Part 1, entry for Oxycoc of Repeats: 0]	done in the f	orm T	Γablet containinς	ј оху	codone l	hydrochloride 5	mg [Maximur	n Quanti	ty: 10; Ni	umber	
	insert in the columns in the order indicated	d, and in alpho	abetic	al order for the coli	ımn h	eaded "Br	and":					
			а	Oxycodone Viatris	MQ	MP NP	C10764 C10766 C10771 C10772	P10766	10	0	20	
						PDP	C10766 C10768	P10766	10	0	20	
			а	Oxycodone Viatris	MQ	MP NP		P10764 P10771	20	0	20	
			а	Oxycodone Viatris	MQ	MP NP	C10764 C10766 C10771 C10772		20	0	20	
			а	Oxycodone Viatris	MQ	MP NP		P10772	20	0	20	
9]	Schedule 1, Part 1, entry for Paclita	xel	a	Oxycodone Viatris	MQ		C10771 C10772	P10772				
9]	Schedule 1, Part 1, entry for Paclitation	xel	а	Oxycodone Viatris	MQ		C10771 C10772	P10772				
9]		<b>xel</b> Injection	a	Oxycodone Viatris Paclitaxin	MQ	PDP	C10771 C10772	P10772	20		20	D(100)
	omit:  Solution concentrate for I.V.	Injection		Paclitaxin	ТВ	PDP MP	C10771 C10772 C10766 C10768	P10772 P10768	20 See Note	0 See Note	20	D(100)
	omit:  Solution concentrate for I.V. infusion 30 mg in 5 mL	Injection		Paclitaxin	ТВ	PDP MP	C10771 C10772 C10766 C10768	P10772 P10768	20 See Note	0 See Note	20	D(100
	Solution concentrate for I.V. infusion 30 mg in 5 mL  Schedule 1, Part 1, entry for Paclitate	Injection		Paclitaxin	ТВ	MP or I.V. infu	C10771 C10772 C10766 C10768	P10772 P10768	See Note	0 See Note	20	D(100)
19] 20] 21]	Solution concentrate for I.V. infusion 30 mg in 5 mL  Schedule 1, Part 1, entry for Paclitate	Injection xel in the for	m Sc	Paclitaxin  Slution concentra  Paclitaxin	TB ate fo	MP or I.V. infu	C10771 C10772 C10766 C10768	P10772 P10768 <b>50 mL</b>	See Note 3	See Note 3	1 1	

	Pack containing 2 tubes eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g	Application to the eye	Poly Visc	IQ	MP NP AO		1	5	1	
			Refresh Night Time	AG	MP NP AO		1	5	1	
			Poly Visc	IQ	MP	P4894	1	11	1	
			Refresh Night Time	AG	MP	P4894	1	11	1	
[22]	Schedule 1, Part 1, entry for Pemetrex infusion 500 mg (as disodium)  omit:	ed in each of	the forms: Powde	r for	I.V. infusion 100 r	mg (as disodium)	; and Powde	er for I.V.		
			Tevatrexed	ТВ	MP		See Note 3	See Note 3	1	D(100
23]	Schedule 1, Part 1, entry for Perindop	ril in the form	Tablet containing	peri	ndopril erbumine	2 mg				
	insert in the columns in the order indicated,	and in alphabetic	cal order for the colu	mn h	eaded "Brand":					
			PERISYL	AL	MP NP		30	5	30	
	Schedule 1, Part 1, entry for Perindop	ril in the form	Tablet containing	peri	ndopril erbumine	4 mg				
[24]	insert in the columns in the order indicated,	and in alphabetic	cal order for the colu	mn h	eaded "Brand":					
[24]			PERISYL	AL	MP NP		30	5	30	
[24]										
	Schedule 1, Part 1, entry for Perindop		•	•	•	8 mg				
[24]	Schedule 1, Part 1, entry for Perindop insert in the columns in the order indicated,		•	•	•	8 mg				

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

hemihydrate 1.25 mg

				PERISYL COMBI 4/1.25	AL	MP NP	C4375	30	5	30	
27]	Schedule 1 substitute:	l, Part 1, entry for Piroxica	am								
riroxicam		Capsule 10 mg	Oral	APO-Piroxicam	TX	PDP	C6214	50	0	50	
						MP NP	C6214	50	3	50	
		Capsule 20 mg	Oral	APO-Piroxicam	TX	PDP	C6214	25	0	25	
						MP NP	C6214	25	3	25	
		Dispersible tablet 20 mg	Oral	Feldene-D	PF	PDP	C6214	25	0	25	
							00044	0.5	•		
28]		l, Part 1, entry for Polyeth	ylene glycol 400	with propylene	glyco	MP NP	C6214	25	3	25	
28]	Schedule 1	Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 28	ylene glycol 400  Application to the eye	Systane				25	5	1	
	omit:	Eye drops 4 mg-3 mg per mL,	Application to the eye			ol .					
28] 29] 30]	omit:	Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 28	Application to the eye	Systane	AQ	AO MP NP	C6172	2	5	1	
29]	omit: Schedule 1 Schedule 1	Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 28	Application to the eye	Systane	AQ e <b>25</b> ı	AO MP NP	C6172	2	5	1	
29]	Schedule 1 Schedule 1 omit:	Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 28	Application to the eye  Iyvinyl alcohol alin in each of the	Systane ne forms: Capsulo	AQ e <b>25</b> ı	AO MP NP	C6172 ule 75 mg; Capsulo	2 e 150 mg; and Ca	5 psule 30	1 00 mg	

#### [32] Schedule 1, Part 1, entry for Salbutamol

omit:

Pressurised inhalation 100 micrograms (as sulfate) per dos 200 doses (CFC-free formulation		Asmol CFC-free	AL MP N	NP	2	5	1	
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## [33] Schedule 1, Part 1, entry for Salbutamol in the form Pressurised inhalation 100 micrograms (as sulfate) per dose with dose counter, 200 doses (CFC-free formulation)

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

#### [34] Schedule 1, Part 1, entry for Somatropin

omit:

Injection 18 i.u. (6 mg) cartridge with 3.15 mL diluent (with preservative)	Injection	Humatrope	LY	MP	C12703 C12704 C12711 C12712 C12722 C12723 C12725 C12726 C12731 C12734 C12738 C12758 C12760 C12765 C12769 C12770 C12771 C12774 C12775 C12779 C12775 C12779 C12780 C12784 C12831 C12832 C12834 C12835 C12858 C12860 C12866 C12884 C12906 C12907 C12922 C13288 C13309 C13346 C13350 C13355 C13356 C13359 C13360 C13363 C13364	3	See Note 1 3	D(100)
Injection 36 i.u. (12 mg) cartridge with 3.15 mL diluent (with	Injection	Humatrope	LY	MP	C12703 C12704 C12711 C12712	See Note 3	See Note 1 3	D(100)

C12725 C12726
C12731 C12734 C12758 C12760 C12765 C12760 C12765 C12760 C12765 C12760 C12776 C12771 C1277 C12771 C12774 C12775 C12779 C12771 C12774 C12776 C12779 C12776 C12779 C12780 C12784 C12785 C12803 C12831 C12832 C12834 C12835 C12836 C12856 C12866 C12860 C12866 C12860 C12866 C12894 C12906 C12907 C12922 C13288 C13360 C13355 C13360 C13355 C13363 C13355 C13363 C13355 C13363 C13355 C13363 C13363 C13364 Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 See Note See Note 1 D(100) with 3.15 m.L diluent (with C1271 C12712 3 3 3 C12725 C12723 C12725 C12723 C12725 C12726 C12736 C12734 C12738 C12756 C12760 C12776 C12771 C12774
C12738 C12758 C12760 C12765 C12769 C12770 C12771 C12774 C12775 C12779 C12770 C12774 C12775 C12779 C12780 C12784 C12780 C12784 C12785 C12803 C12831 C12832 C12831 C12832 C12836 C12860 C12856 C12860 C12856 C12864 C12906 C12907 C12906 C12907 C12902 C13288 C13309 C13346 C13309 C13346 C13350 C13355 C13355 C13355 C13356 C13355 C13356 C13559 C13364  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 with 3.15 mL diluent (with C12714 preservative)  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 C12711 C12712 preservative)  C12715 C12726 C12736 C12736 C12736 C12736 C12736 C12736 C12736 C12766 C12731 C12734 C12737 C12774 C12777 C12777
C12766 C12765 C12766 C12770 C12771 C12774 C12775 C12779 C1278 C12779 C12780 C12784 C12785 C12803 C1281 C12832 C12834 C12832 C12835 C12836 C12836 C12884 C12906 C12907 C1282 C12836 C13305 C13352 C13351 C13352 C13356 C13359 C13356 C13359 C13360 C13363 C13361 C1353 C13364  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 See Note See Note 1 D(100) with 3.15 mL diluent (with C12711 C12712 3 3 3 C12725 C12726 C12725 C12726 C12725 C12726 C12731 C12734 C12734 C12734 C12736 C12766 C12760 C12765 C12760 C12765 C12760 C12770 C12777 C127774
C12769 C12770 C12771 C12774 C12775 C12774 C12776 C12784 C12785 C12803 C12836 C12835 C12836 C12835 C12836 C12836 C12836 C12884 C12906 C12907 C12922 C13288 C13300 C13346 C13300 C13346 C13350 C13355 C13355 C13355 C13356 C13355 C13356 C13355 C13360 C13363 C13364  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 With 3.15 mL diluent (with C12736 C12774 With 3.15 mL diluent (with C12736 C127786 C12776 C12776 C12777 C12777 C12777 C12777
C12771 C12774 C12775 C12779 C12778 C12779 C12778 C12778 C12778 C12774 C12775 C12779 C12784 C12780 C12784 C12785 C12832 C12831 C12832 C12834 C12835 C12858 C12860 C12856 C12866 C12866 C12884 C12906 C12907 C12922 C13288 C13309 C13346 C13350 C13352 C13353 C13355 C13356 C13359 C13350 C13363 C13350 C13363 C13360 C13363 C13360 C13363 C13360 C13363 C13264  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 with 3.15 mL diluent (with C12711 C12712 3 3 3 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
C12775 C12779 C12780 C12784 C12785 C12803 C12815 C12803 C1283 C12835 C12836 C12835 C12868 C12860 C12868 C12884 C12906 C12897 C12907 C1292 C13288 C13309 C13346 C13350 C13352 C13353 C13355 C13356 C13355 C13356 C13359 C13366 C13360 C13864  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 See Note See Note 1 D(100) with 3.15 mL diluent (with C12711 C12712 3 3 3 C12726 C12726 C12731 C12724 C12725 C12723 C12726 C12726 C12731 C12734 C12726 C12765 C12760 C12776 C12771 C12774
C12775 C12779 C12780 C12784 C12785 C12803 C12815 C12803 C1283 C12835 C12836 C12835 C12868 C12860 C12868 C12884 C12906 C12897 C12907 C1292 C13288 C13309 C13346 C13350 C13352 C13353 C13355 C13356 C13355 C13356 C13359 C13366 C13360 C13864  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 See Note See Note 1 D(100) with 3.15 mL diluent (with C12711 C12712 3 3 3 C12726 C12726 C12731 C12724 C12725 C12723 C12726 C12726 C12731 C12734 C12726 C12765 C12760 C12776 C12771 C12774
C12780 C12784 C12785 C12803 C12831 C12832 C12834 C12835 C12838 C128360 C12866 C12884 C12906 C12907 C12926 C12907 C12922 C13288 C13309 C13346 C13350 C13352 C13350 C13355 C13350 C13355 C13360 C13359 C13360 C13363 C1364  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 with 3.15 mL diluent (with C12712 3 3 3 C12724 preservative) C12725 C12723 C12726 C12723 C12726 C12726 C12731 C12726 C12736 C12765 C12769 C12770 C12771 C12774
C12785 C12803 C12831 C12832 C12834 C12835 C12858 C12860 C12858 C12860 C12866 C12884 C12906 C12907 C12922 C13288 C13309 C13346 C13309 C13346 C13350 C13355 C13355 C13355 C13356 C13359 C13360 C13359 C13360 C13360 C13360 C13360 C13360 C13360 C13360 C13260 C13260 C1271 C12712 C12723 C12721 C12712 3 3 C12726 C12726 C12731 C12734 C12736 C12736 C12736 C12756 C12760 C12765 C12770 C12771 C12774
C12831 C12832 C12834 C12835 C12858 C12860 C12866 C12860 C12866 C12807 C12907 C12902 C13288 C12907 C12922 C13288 C13305 C13356 C13350 C13352 C13350 C13355 C13350 C13355 C13350 C13353 C13364  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 See Note See Note 1 D(100) with 3.15 mL diluent (with C12711 C12712 3 3 3 C12711 C12712 preservative)  C12715 C12723 C12725 C12726 C12736 C12736 C12737 C12758 C12776 C12776 C12771 C12774
C12834 C12835 C12860 C12864 C12866 C12884 C12906 C12907 C12922 C13288 C13309 C13346 C13350 C13352 C13353 C13355 C13353 C13355 C13356 C13359 C13360 C13363 C13364  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 See Note See Note 1 D(100) with 3.15 mL diluent (with C12711 C12712 3 3 3 C12725 C12726 C12725 C12726 C12725 C12726 C12726 C12723 C12726 C12728 C12736 C12758 C12760 C12776 C12771 C12771 C12771 C12777
C12868 C12860 C12868 C12884 C12906 C12907 C12922 C13288 C13309 C13346 C13350 C13352 C13353 C13355 C13353 C13355 C13356 C13359 C13360 C13363 C13364  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 See Note See Note 1 D(100) with 3.15 mL diluent (with C12711 C12712 3 3 3 C12725 C12726 C12731 C12734 C12725 C12726 C12731 C12734 C12736 C12755 C12760 C12770 C12771 C12770
C12866 C12884 C12906 C12907 C12922 C13288 C13309 C13346 C13350 C13355 C13355 C13355 C13356 C13355 C13360 C13363 C13360 C13363 C13364  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 See Note See Note 1 D(100) with 3.15 mL diluent (with C12712 3 3 3 preservative) C12722 C12723 C12725 C12726 C12731 C12734 C12738 C12758 C12760 C12765 C12760 C12770 C12771 C12774
C12906 C12907 C12922 C13288 C13309 C13346 C13350 C13352 C13353 C13355 C13360 C13359 C13360 C13363 C13364  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 See Note See Note 1 D(100) with 3.15 mL diluent (with C12711 C12712 3 3 preservative) C12722 C12723 C12726 C12726 C12726 C12731 C12734 C12738 C12758 C12760 C12776 C12771 C12777 C127771 C127774
C12922 C13288 C13306 C13346 C13350 C13352 C13353 C13355 C13356 C13359 C13360 C13363 C13364  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 See Note See Note 1 D(100) with 3.15 mL diluent (with C12711 C12712 3 3 3 reservative)  C12722 C12723 C12725 C12726 C12731 C12734 C12738 C12758 C12760 C12776 C12771 C12770 C12771 C12774
C13309 C13346 C13350 C13352 C13353 C13355 C13356 C13359 C13360 C13363 C13364  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 See Note See Note 1 D(100) with 3.15 mL diluent (with C12711 C12712 3 3 3 preservative)  C12722 C12723 C12725 C12726 C12731 C12734 C12738 C12758 C12760 C12776 C12777 C12774
C13350 C13352 C13356 C13355 C13356 C13359 C13360 C13363 C13364  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 See Note See Note 1 D(100) with 3.15 mL diluent (with C12711 C12712 3 3 3 preservative)  C12725 C12726 C12731 C12734 C12738 C12758 C12760 C12776 C12771 C12770 C12771 C12777
C13353 C13355 C13356 C13359 C13360 C13363 C13364  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 See Note See Note 1 D(100) with 3.15 mL diluent (with C12711 C12712 3 3 preservative)  C12722 C12723 C12725 C12726 C12731 C12734 C12738 C12758 C12760 C12765 C12760 C12770 C12771 C12774
C13356 C13359 C13360 C13363 C13364  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 See Note See Note 1 D(100) with 3.15 mL diluent (with preservative)  C12711 C12712 3 3 3 C12722 C12723 C12725 C12726 C12731 C12734 C12738 C12758 C12760 C12765 C12769 C12770 C12771 C12774
C13360 C13363 C13364  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 See Note See Note 1 D(100) with 3.15 mL diluent (with c12711 C12712 3 3 3 preservative)  C12722 C12723 C12725 C12726 C12731 C12734 C12738 C12758 C12760 C12765 C12760 C12770 C12771 C12774
C13364  Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 See Note See Note 1 D(100) with 3.15 mL diluent (with C12711 C12712 3 3 3 preservative)  C12722 C12723 C12726 C12726 C12725 C12726 C12731 C12734 C12738 C12758 C12760 C12760 C12770 C12771 C12774
Injection 72 i.u. (24 mg) cartridge Injection Humatrope LY MP C12703 C12704 See Note See Note 1 D(100) with 3.15 mL diluent (with preservative) C12722 C12723 C12726 C12726 C12731 C12734 C12734 C12738 C12758 C12760 C12765 C12760 C12771 C12774
with 3.15 mL diluent (with C12711 C12712 3 3 3 preservative) C12722 C12723 C12725 C12726 C12731 C12734 C12738 C12758 C12760 C12765 C12769 C12770 C12771 C12774
with 3.15 mL diluent (with C12711 C12712 3 3 3 preservative) C12722 C12723 C12725 C12726 C12731 C12734 C12738 C12758 C12760 C12765 C12769 C12770 C12771 C12774
preservative)  C12722 C12723 C12725 C12726 C12731 C12734 C12738 C12758 C12760 C12765 C12769 C12770 C12771 C12774
C12725 C12726 C12731 C12734 C12738 C12758 C12760 C12765 C12769 C12770 C12771 C12774
C12731 C12734 C12738 C12758 C12760 C12765 C12769 C12770 C12771 C12774
C12738 C12758 C12760 C12765 C12769 C12770 C12771 C12774
C12760 C12765 C12769 C12770 C12771 C12774
C12769 C12770 C12771 C12774
C12771 C12774
C4077F C40770
C12775 C12779
C12780 C12784
C12785 C12803
C12831 C12832
C12834 C12835
C12858 C12860
C12866 C12884
C12906 C12907
C12922 C13288
C13309 C13346
C13350 C13352
C13353 C13355

						C13356 C13359 C13360 C13363 C13364				
35]	Schedule 1, Part 1, entry for Zanubrutinib omit from the column headed "Circumstances": C1257	<b>'</b> 3								
36]	Schedule 1, Part 1, entry for Zoledronic acid in insert in the columns in the order indicated, and in alph		-				nonohydrate)	in 5 mL		
		а	Zoledronate-DRLA 4	RZ	MP	C5605 C5703 C5704 C5735 C9268 C9304	1	11	1	PB(10
						C9317 C9328				
37]	Schedule 1, Part 1, entry for Zoledronic acid in substitute:	the fo	orm Solution for I.	.V. in	ıfusion		) in 100 mL			
37]	•	the fo	orm Solution for I.  Aclasta	.V. in			) in 100 mL	0	1	
37]	substitute:  Solution for I.V. infusion 5 mg (as Injection			НХ		5 mg (as monohydrate) C5710 C6308		0	1	
37]	substitute:  Solution for I.V. infusion 5 mg (as Injection	а	Aclasta	HX SZ	MP	5 mg (as monohydrate)  C5710 C6308 C6313 C6318 C5710 C6308	1			
37]	substitute:  Solution for I.V. infusion 5 mg (as Injection	a a	Aclasta Osteovan	HX SZ TX	MP MP	5 mg (as monohydrate)  C5710 C6308 C6313 C6318  C5710 C6308 C6313 C6318  C5710 C6308	1	0	1	

Chlorpromazine Tablet containing chlorpromazine Oral Largactil SW MP NP 100 5 100 hydrochloride 10 mg

#### [39] Schedule 1, Part 2, after entry for Interferon beta-1a in the form Solution for injection 132 micrograms in 1.5 mL multidose cartridge

77	10	0	1.0	t	٠

Losartan	Tablet containing losartan potassium 25 mg	Oral	Cozavan	AF	MP NP	30	5	30
	Tablet containing losartan potassium 50 mg	Oral	Cozavan	AF	MP NP	60	5	30

# [40] Schedule 1, Part 2, after entry for Pindolol

insert:

Piroxicam	Dispersible tablet 10 mg	Oral	Mobilis D-10	AF	PDP	C6214		50	0	50
					MP NP	C6214		50	3	50
Polyethylene glycol 400 with propylene glycol	Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 28	Application to the eye	Systane	AQ	AO MP NP	C6172		2	5	1
Polyvinyl alcohol	Eye drops 14 mg per mL, 15 mL	Application to a the eye	Liquifilm Tears	AG	MP	C6073 C6098	P6073	1	5	1
					NP	C6073		1	5	1
					AO	C6120		1	5	1
		а	PVA Tears	PE	MP	C6073 C6098	P6073	1	5	1
					NP	C6073		1	5	1
					AO	C6120		1	5	1
		а	Liquifilm Tears	AG	MP	C6073 C6098	P6098	1	11	1
		а	PVA Tears	PE	MP	C6073 C6098	P6098	1	11	1
Propranolol	Tablet containing propranolol hydrochloride 160 mg	Oral	Deralin 160	AF	MP NP			50	5	50

# [41] Schedule 1, Part 2, omit entry for Rituximab

# [42] Schedule 3, details relevant to Responsible Person code GO

omit from the column headed "Responsible Person": Mylan Health Pty Ltd substitute: Viatris Pty Ltd

[43] Schedule 3, details relevant to Responsible Person code GT

omit from the column headed "Responsible Person": Mylan Health Pty Ltd substitute: Viatris Pty Ltd

- [44] Schedule 4, Part 1, entry for Donepezil
  - (a) omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)" for circumstances code "C10099": Compliance with Authority Required procedures

    substitute: Compliance with Written Authority Required procedures
  - (b) omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)" for circumstances code "C10100": Compliance with Authority Required procedures

    substitute: Compliance with Written Authority Required procedures
- [45] Schedule 4, Part 1, entry for Galantamine
  - (a) omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)" for circumstances code "C10099": Compliance with Authority Required procedures

    substitute: Compliance with Written Authority Required procedures
  - (b) omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)" for circumstances code "C10100": Compliance with Authority Required procedures

    \*\*substitute:\* Compliance with Written Authority Required procedures\*\*
- [46] Schedule 4, Part 1, entry for Ipilimumab
  - (a) omit:

Induction treatment Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND	Compliance with Authority Required procedures - Streamlined Authority Code 10122
The condition must not be ocular or uveal melanoma; AND The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition. Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks. Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	

- (b) omit from the column headed "Purposes Code" for the circumstance code "C11930": P11930
- (c) insert in numerical order after existing text:

C13841	Unresectable Stage III or Stage IV malignant melanoma	Compliance with
	Induction treatment Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the	Authority Required procedures -
	treatment of unresectable Stage III or Stage IV malignant melanoma; AND	Streamlined Authority
	Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND	Code 13841
	The condition must not be ocular or uveal melanoma; AND	
	The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.	
	Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.	
	Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.	
	The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	

#### Schedule 4, Part 1, entry for Memantine [4/]

- omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)" for circumstances code "C10098": Compliance with (a) **Authority Required procedures** substitute: Compliance with Written Authority Required procedures
- omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)" for circumstances code "C10184": Compliance with **Authority Required procedures** substitute: Compliance with Written Authority Required procedures

#### [48] Schedule 4, Part 1, entry for Nivolumab

(a) omit:

	C9214	Maintenance treatment Patient must have previously received of up to maximum 4 doses of PBS-subsidised combined therapy with nivolumab and ipilimumab as induction for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority Code 9214
<b>(b)</b> om	it:		
	C10195	Induction treatment Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND	Compliance with Authority Required procedures - Streamlined Authority Code 10195

	Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND The condition must not be ocular or uveal melanoma; AND The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition. Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks. Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.	
(c) insert in numerica	l order after existing text:	1
C13839	Unresectable Stage III or Stage IV malignant melanoma Maintenance treatment Patient must have previously received of up to maximum 4 doses of PBS-subsidised combined therapy with nivolumab and ipilimumab as induction for this condition; AND The treatment must be as monotherapy for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this PBS indication. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authorit Code 13839
C13852	Unresectable Stage III or Stage IV malignant melanoma Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements for combination induction therapy Patient must have received non-PBS-subsidised treatment with nivolumab in combination with ipilimumab for this PBS indication prior to 1 March 2023; AND Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 prior to commencing non-PBS-subsidised treatment; AND The condition must not be ocular or uveal melanoma; AND The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition. Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks. Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.	Compliance with Authority Required procedures - Streamlined Authorit Code 13852
C13853	Unresectable Stage III or Stage IV malignant melanoma Induction treatment Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND The condition must not be ocular or uveal melanoma; AND The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition. Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks. Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.	Compliance with Authority Required procedures - Streamlined Authori Code 13853
C13863	Unresectable Stage III or Stage IV malignant melanoma Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements for maintenance treatment Patient must have previously received of up to maximum 4 doses of PBS-subsidised ipilimumab combined therapy with non-PBS-subsidised nivolumab as induction for this condition prior to 1 March 2023; AND	Compliance with Authority Required procedures - Streamlined Authori

	The treatment must be as monotherapy for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this PBS indication. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	Code 13863
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### [49] Schedule 4, Part 1, omit entry for Rituximab

### [50] Schedule 4, Part 1, entry for Rivastigmine

- (a) omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)" for circumstances code "C10099": Compliance with Authority Required procedures

  \*\*substitute:\* Compliance with Written Authority Required procedures\*\*
- (b) omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)" for circumstances code "C10100": Compliance with Authority Required procedures

  \*\*substitute: Compliance with Written Authority Required procedures\*\*

### [51] Schedule 4, Part 1, entry for Somatropin

(a) *omit*:

C12734	Initial treatment	Compliance with Written Authority Required procedures
	Patient must be male and must not have a height greater than or equal to 167.7 cm; OR Patient must be female and must not have a height greater than or equal to 155.0 cm; AND	

		Patient must be male and must not have a bone age of 15.5 years or more; OR Patient must be female and must not have a bone age of 13.5 years or more. Patient must be prepubertal. An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed). The authority application must be in writing and must include:  1. A completed authority prescription form; AND 2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND	
		3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR (b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1 <sup>st</sup> percentile for age and sex; AND 4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND 5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m <sup>2</sup> ; AND	
		6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND 7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records	
		must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
(b) om	it:		<del>,</del>
	C12835		Compliance with Written Authority Required procedures
		the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing	

treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment period, whichever applies), unless response was affected by an adverse reaction to growth normone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for
the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing
treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND
Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and
Bloom syndromes; AND

Patient must not have an active tumour or evidence of tumour growth or activity; AND

Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application; AND

Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>; AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more; AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Patient must be prepubertal.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

- 1. A completed authority prescription form; AND
- 2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
- 3. Recent growth data (height and weight, not older than three months): AND
- 4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less);
- 5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; AND
- 6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
- 7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m²prescribers should seek reclassification to the indication short stature and slow growth.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes

	control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.
(c) omit:	
C12906	Short stature associated with chronic renal insufficiency Recommencement of treatment as a reclassified patient Patient must have previously received treatment under the PBS \$100 Growth Hormone Program (treatment) under a category other than short stature associated with chronic renal insufficiency; AND Patient must have had a lapse in treatment, AND The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical Illness; OR The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g., enal transplant); OR The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g., enal transplant); OR The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period, of 32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g., enal trans

C12907	Patient must be male and must not have a height greater than or equal to 167.7cm; OR Patient must be female and must not have a bone age of 15.5 years or more; OR Patient must be female and must not have a bone age of 15.5 years or more. Patient must be female and must not have a bone age of 15.5 years or more. Patient must be female and must not have a bone age of 13.5 years or more. Patient must be prepubertal. Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics. An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years. The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed). The authority application must be in writing and must include:  1. A completed authority prescription form; AND 2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND 3. (a) An iminimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment); OR (b) Height and weight measurements from within three mo	Compliance with Written
C12907	Short stature associated with chronic renal insufficiency Continuing treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category; AND	Compliance with Written Authority Required procedures

Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND

Patient must not have an active tumour or evidence of tumour growth or activity; AND

Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application;

Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>; AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm; AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Patient must be prepubertal.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

- 1. A completed authority prescription form; AND
- 2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
- 3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
- 4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
- 5. The final adult height (in cm) of the patient's mother and father (where available); AND
- 6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes

Continuing treatment as a reclassified patient Patient must have previously received treatment under the PBS \$100 Growth Hormone Program (treatment) under a category other than short stature associated with chronic renal insufficiency; AND The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies). OR The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies). Unless response was affected by a significant medical lilness; OR The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an aignificant medical lilness; OR The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or gre			control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
Continuing treatment as a reclassified patient Patient must have previously received treatment under the PBS \$100 Growth Hormone Program (treatment) under a category other than short stature associated with chronic renal insufficiency; AND The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies). OR The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR The treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR The treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND Patient must have had both a height above the 1°m at or below the 25°m percentile for pas and sex immediately prior to commencing treatment and a growth velocity less than or equal to the treatment period and 26 weeks for	(d) omit	:		
			Continuing treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with chronic renal insufficiency; AND The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week	procedures
undergone a 12 month period of observation following the transplant; AND			Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m²measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m²measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have	

Patient must be female and must not have a height greater than or equal to 155.0cm; AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Patient must be prepubertal.

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

- 1. A completed authority prescription form; AND
- 2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
- 3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
- (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1<sup>st</sup>percentile for age and sex immediately prior to commencing treatment; AND
- 4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m<sup>2</sup>; AND
- 5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
- 6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months: AND
- 7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### [52] Schedule 4, Part 1, entry for Zanubrutinib

omit:

C12573	Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements	Compliance with Authority Required procedures
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- [53] Schedule 5, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe [GRP-25058] insert in alphabetical order in the column headed "Brand": Yuflyma
- [54] Schedule 5, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen [GRP-25060] insert in alphabetical order in the column headed "Brand": Yuflyma
- [55] Schedule 5, after entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [GRP-25060]

insert:

GRP-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
GRP-27088	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Yuflyma
	Injection 40 mg in 0.8 mL pre-filled pen	,	Amgevita Hadlima Hyrimoz Idacio

- [56] Schedule 5, entry for Clopidogrel in the form Tablet 75 mg (as hydrogen sulfate) omit from the column headed "Brand": Blooms the Chemist Clopidogrel
- [57] Schedule 5, entry for Perindopril in the form Tablet containing perindopril erbumine 4 mg [GRP-15442] insert in alphabetical order in the column headed "Brand": PERISYL
- [58] Schedule 5, entry for Perindopril in the form Tablet containing perindopril erbumine 8 mg [GRP-15525] insert in alphabetical order in the column headed "Brand": PERISYL
- [59] Schedule 5, entry for Perindopril in the form Tablet containing perindopril erbumine 2 mg [GRP-15965] insert in alphabetical order in the column headed "Brand": PERISYL
- [60] Schedule 5, entry for Perindopril with indapamide in the form Tablet containing perindopril erbumine 4 mg with indapamide hemihydrate 1.25 mg

insert in alphabetical order in the column headed "Brand": PERISYL COMBI 4/1.25

[61] Schedule 5, entry for Salbutamol

omit:

GRP-24211	Pressurised inhalation 100 micrograms (as sulfate) per dose, 200 doses (CFC-free formulation)	Inhalation by mouth	Asmol CFC-free
	Pressurised inhalation 100 micrograms (as sulfate) per dose with dose counter, 200 doses (CFC-free formulation)	,	Asmol CFC-Free with dose counter Ventolin CFC-Free with dose counter Zempreon CFC-Free with dose counter