



**PB 105 of 2023**

# **National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 11)**

*National Health Act 1953*

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I, EDEN SIMON, 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                    30 October 2023

**EDEN SIMON**  
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. 11)*.
- (2) This Instrument may also be cited as PB 105 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.

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Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. <i>The whole of this instrument</i>	<i>1 November 2023</i>	<i>1 November 2023</i>

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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

*substitute:*

Abatacept	Injection 125 mg in 1 mL single dose autoinjector	Injection	Orenzia ClickJect	BQ	MP	C14488 C14507 C14519 C14522 C14560 C14583 C14604	P14488 P14522 P14560 P14583	4	3	4	
					MP	C14488 C14507 C14519 C14522 C14560 C14583 C14604	P14507 P14519 P14604	4	5	4	
	Injection 125 mg in 1 mL single dose pre-filled syringe	Injection	Orenzia	BQ	MP	C14488 C14507 C14519 C14522 C14560 C14583 C14604	P14488 P14522 P14560 P14583	4	3	4	
					MP	C14488 C14507 C14519 C14522 C14560 C14583 C14604	P14507 P14519 P14604	4	5	4	
	Powder for I.V. infusion 250 mg	Injection	Orenzia	BQ	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)
					MP	C14555 C14604		3	5	1	PB(100)

[2] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen [Brand: Humira; Maximum Quantity: 2; Number of Repeats: 0]

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11720**
- (c) omit from the column headed "Circumstances": **C11769 C11772**
- (d) omit from the column headed "Circumstances": **C13550**

- 
- (e) *omit from the column headed "Circumstances": C13648*
  - (f) *omit from the column headed "Circumstances": C14058*
  - (g) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14498 C14499 C14507*

**[3] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen [Brand: Yuflyma; Maximum Quantity: 2; Number of Repeats: 0]**

- (a) *omit from the column headed "Circumstances": C8638*
- (b) *omit from the column headed "Circumstances": C11605*
- (c) *omit from the column headed "Circumstances": C11720*
- (d) *omit from the column headed "Circumstances": C11769 C11772*
- (e) *omit from the column headed "Circumstances": C13550*
- (f) *omit from the column headed "Circumstances": C13648*
- (g) *omit from the column headed "Circumstances": C14058*
- (h) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590*

**[4] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen [Brand: Humira; Maximum Quantity: 2; Number of Repeats: 2]**

- (a) *omit from the column headed "Circumstances": C8638*
- (b) *omit from the column headed "Circumstances": C11720*
- (c) *omit from the column headed "Circumstances": C11769 C11772*
- (d) *omit from the column headed "Circumstances": C13550*
- (e) *omit from the column headed "Circumstances": C13648*
- (f) *omit from the column headed "Circumstances": C14058*
- (g) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14498 C14499 C14507*

**[5] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen [Brand: Yuflyma; Maximum Quantity: 2; Number of Repeats: 2]**

- (a) *omit from the column headed "Circumstances": C8638*

- 
- (b) omit from the column headed "Circumstances": **C11605**
  - (c) omit from the column headed "Circumstances": **C11720**
  - (d) omit from the column headed "Circumstances": **C11769 C11772**
  - (e) omit from the column headed "Circumstances": **C13550**
  - (f) omit from the column headed "Circumstances": **C13648**
  - (g) omit from the column headed "Circumstances": **C14058**
  - (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[6] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen [Brand: Humira; Maximum Quantity: 2; Number of Repeats: 3]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11720**
- (c) omit from the column headed "Circumstances": **C11769 C11772**
- (d) omit from the column headed "Circumstances": **C13550**
- (e) omit from the column headed "Circumstances": **C13648**
- (f) omit from the column headed "Circumstances": **C14058**
- (g) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14498 C14499 C14507**
- (h) omit from the column headed "Purposes": **P8638**
- (i) omit from the column headed "Purposes": **P13550**
- (j) omit from the column headed "Purposes": **P13648**
- (k) omit from the column headed "Purposes": **P14058**
- (l) insert in numerical order in the column headed "Purposes": **P14483 P14486 P14488 P14498**

**[7] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen [Brand: Yuflyma; Maximum Quantity: 2; Number of Repeats: 3]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**

- 
- (c) omit from the column headed "Circumstances": **C11720**
  - (d) omit from the column headed "Circumstances": **C11769 C11772**
  - (e) omit from the column headed "Circumstances": **C13550**
  - (f) omit from the column headed "Circumstances": **C13648**
  - (g) omit from the column headed "Circumstances": **C14058**
  - (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
  - (i) omit from the column headed "Purposes": **P8638**
  - (j) omit from the column headed "Purposes": **P13550**
  - (k) omit from the column headed "Purposes": **P13648**
  - (l) omit from the column headed "Purposes": **P14058**
  - (m) insert in numerical order in the column headed "Purposes": **P14483 P14486 P14488 P14496 P14498 P14568 P14590**

**[8] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen [Brand: Humira; Maximum Quantity: 2; Number of Repeats: 4]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11720**
- (c) omit from the column headed "Circumstances": **C11769 C11772**
- (d) omit from the column headed "Circumstances": **C13550**
- (e) omit from the column headed "Circumstances": **C13648**
- (f) omit from the column headed "Circumstances": **C14058**
- (g) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14498 C14499 C14507**

**[9] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen [Brand: Yuflyma; Maximum Quantity: 2; Number of Repeats: 4]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**

- 
- (d) omit from the column headed "Circumstances": **C11769 C11772**
  - (e) omit from the column headed "Circumstances": **C13550**
  - (f) omit from the column headed "Circumstances": **C13648**
  - (g) omit from the column headed "Circumstances": **C14058**
  - (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[10] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen [Brand: Humira; Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only: Nil]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11720**
- (c) omit from the column headed "Circumstances": **C11769 C11772**
- (d) omit from the column headed "Circumstances": **C13550**
- (e) omit from the column headed "Circumstances": **C13648**
- (f) omit from the column headed "Circumstances": **C14058**
- (g) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14498 C14499 C14507**
- (h) omit from the column headed "Purposes": **P11720**
- (i) omit from the column headed "Purposes": **P11769 P11772**
- (j) insert in numerical order in the column headed "Purposes": **P14493 P14499 P14507**

**[11] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen [Brand: Yuflyma; Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only: Nil]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**
- (d) omit from the column headed "Circumstances": **C11769 C11772**
- (e) omit from the column headed "Circumstances": **C13550**
- (f) omit from the column headed "Circumstances": **C13648**



- 
- (g) *omit from the column headed "Circumstances": C14058*
- (h) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590*
- (i) *omit from the column headed "Purposes": P11605*
- (j) *omit from the column headed "Purposes": P11720*
- (k) *omit from the column headed "Purposes": P11769 P11772*
- (l) *insert in numerical order in the column headed "Purposes": P14493 P14499 P14507 P14567*
- [12] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen [Brand: Humira; Maximum Quantity: 4; Number of Repeats: 2]**
- (a) *omit from the column headed "Circumstances": C8638*
- (b) *omit from the column headed "Circumstances": C11720*
- (c) *omit from the column headed "Circumstances": C11769 C11772*
- (d) *omit from the column headed "Circumstances": C13550*
- (e) *omit from the column headed "Circumstances": C13648*
- (f) *omit from the column headed "Circumstances": C14058*
- (g) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507*
- [13] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen [Brand: Yuflyma; Maximum Quantity: 4; Number of Repeats: 2]**
- (a) *omit from the column headed "Circumstances": C8638*
- (b) *omit from the column headed "Circumstances": C11605*
- (c) *omit from the column headed "Circumstances": C11720*
- (d) *omit from the column headed "Circumstances": C11769 C11772*
- (e) *omit from the column headed "Circumstances": C13550*
- (f) *omit from the column headed "Circumstances": C13648*
- (g) *omit from the column headed "Circumstances": C14058*
- (h) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567*
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**C14568 C14590**

**[14] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen [Brand: Humira; Maximum Quantity: 4; Number of Repeats: 5]**

(a) *omit from the column headed "Circumstances":* **C8638**

(b) *omit from the column headed "Circumstances":* **C11720**

(c) *omit from the column headed "Circumstances":* **C11769 C11772**

(d) *omit from the column headed "Circumstances":* **C13550**

(e) *omit from the column headed "Circumstances":* **C13648**

(f) *omit from the column headed "Circumstances":* **C14058**

(g) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14498 C14499 C14507**

**[15] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen [Brand: Yuflyma; Maximum Quantity: 4; Number of Repeats: 5]**

(a) *omit from the column headed "Circumstances":* **C8638**

(b) *omit from the column headed "Circumstances":* **C11605**

(c) *omit from the column headed "Circumstances":* **C11720**

(d) *omit from the column headed "Circumstances":* **C11769 C11772**

(e) *omit from the column headed "Circumstances":* **C13550**

(f) *omit from the column headed "Circumstances":* **C13648**

(g) *omit from the column headed "Circumstances":* **C14058**

(h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[16] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen [Brand: Humira; Maximum Quantity: 6; Number of Repeats: 0]**

(a) *omit from the column headed "Circumstances":* **C8638**

(b) *omit from the column headed "Circumstances":* **C11720**

(c) *omit from the column headed "Circumstances":* **C11769 C11772**

- 
- (d) omit from the column headed "Circumstances": **C13550**
  - (e) omit from the column headed "Circumstances": **C13648**
  - (f) omit from the column headed "Circumstances": **C14058**
  - (g) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14498 C14499 C14507**

**[17] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen [Brand: Yuflyma; Maximum Quantity: 6; Number of Repeats: 0]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**
- (d) omit from the column headed "Circumstances": **C11769 C11772**
- (e) omit from the column headed "Circumstances": **C13550**
- (f) omit from the column headed "Circumstances": **C13648**
- (g) omit from the column headed "Circumstances": **C14058**
- (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[18] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe [Brand: Humira; Maximum Quantity: 2; Number of Repeats: 0]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11720**
- (c) omit from the column headed "Circumstances": **C11769 C11772**
- (d) omit from the column headed "Circumstances": **C13550**
- (e) omit from the column headed "Circumstances": **C13648**
- (f) omit from the column headed "Circumstances": **C14058**
- (g) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14498 C14499 C14507**

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- [19] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe [Brand: Yuflyma; Maximum Quantity: 2; Number of Repeats: 0]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11605**
  - (c) *omit from the column headed "Circumstances":* **C11720**
  - (d) *omit from the column headed "Circumstances":* **C11769 C11772**
  - (e) *omit from the column headed "Circumstances":* **C13550**
  - (f) *omit from the column headed "Circumstances":* **C13648**
  - (g) *omit from the column headed "Circumstances":* **C14058**
  - (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
- [20] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe [Brand: Humira; Maximum Quantity: 2; Number of Repeats: 2]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11720**
  - (c) *omit from the column headed "Circumstances":* **C11769 C11772**
  - (d) *omit from the column headed "Circumstances":* **C13550**
  - (e) *omit from the column headed "Circumstances":* **C13648**
  - (f) *omit from the column headed "Circumstances":* **C14058**
  - (g) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14498 C14499 C14507**
- [21] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe [Brand: Yuflyma; Maximum Quantity: 2; Number of Repeats: 2]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11605**
  - (c) *omit from the column headed "Circumstances":* **C11720**
  - (d) *omit from the column headed "Circumstances":* **C11769 C11772**
  - (e) *omit from the column headed "Circumstances":* **C13550**
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- (f) omit from the column headed "Circumstances": **C13648**
  - (g) omit from the column headed "Circumstances": **C14058**
  - (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[22] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe [Brand: Humira; Maximum Quantity: 2; Number of Repeats: 3]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11720**
- (c) omit from the column headed "Circumstances": **C11769 C11772**
- (d) omit from the column headed "Circumstances": **C13550**
- (e) omit from the column headed "Circumstances": **C13648**
- (f) omit from the column headed "Circumstances": **C14058**
- (g) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14498 C14499 C14507**
- (h) omit from the column headed "Purposes": **P8638**
- (i) omit from the column headed "Purposes": **P13550**
- (j) omit from the column headed "Purposes": **P13648**
- (k) omit from the column headed "Purposes": **P14058**
- (l) insert in numerical order in the column headed "Purposes": **P14483 P14486 P14488 P14498**

**[23] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe [Brand: Yuflyma; Maximum Quantity: 2; Number of Repeats: 3]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**
- (d) omit from the column headed "Circumstances": **C11769 C11772**
- (e) omit from the column headed "Circumstances": **C13550**
- (f) omit from the column headed "Circumstances": **C13648**

- 
- (g) *omit from the column headed "Circumstances": C14058*
  - (h) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590*
  - (i) *omit from the column headed "Purposes": P8638*
  - (j) *omit from the column headed "Purposes": P13550*
  - (k) *omit from the column headed "Purposes": P13648*
  - (l) *omit from the column headed "Purposes": P14058*
  - (m) *insert in numerical order in the column headed "Purposes": P14483 P14486 P14488 P14496 P14498 P14568 P14590*

**[24] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe [Brand: Humira; Maximum Quantity: 2; Number of Repeats: 4]**

- (a) *omit from the column headed "Circumstances": C8638*
- (b) *omit from the column headed "Circumstances": C11720*
- (c) *omit from the column headed "Circumstances": C11769 C11772*
- (d) *omit from the column headed "Circumstances": C13550*
- (e) *omit from the column headed "Circumstances": C13648*
- (f) *omit from the column headed "Circumstances": C14058*
- (g) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14498 C14499 C14507*

**[25] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe [Brand: Yuflyma; Maximum Quantity: 2; Number of Repeats: 4]**

- (a) *omit from the column headed "Circumstances": C8638*
- (b) *omit from the column headed "Circumstances": C11605*
- (c) *omit from the column headed "Circumstances": C11720*
- (d) *omit from the column headed "Circumstances": C11769 C11772*
- (e) *omit from the column headed "Circumstances": C13550*
- (f) *omit from the column headed "Circumstances": C13648*
- (g) *omit from the column headed "Circumstances": C14058*

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(h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

[26] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe [Brand: Humira; Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only: Nil]**

(a) *omit from the column headed "Circumstances":* **C8638**

(b) *omit from the column headed "Circumstances":* **C11720**

(c) *omit from the column headed "Circumstances":* **C11769 C11772**

(d) *omit from the column headed "Circumstances":* **C13550**

(e) *omit from the column headed "Circumstances":* **C13648**

(f) *omit from the column headed "Circumstances":* **C14058**

(g) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14498 C14499 C14507**

(h) *omit from the column headed "Purposes":* **P11720**

(i) *omit from the column headed "Purposes":* **P11769 P11772**

(j) *insert in numerical order in the column headed "Purposes":* **P14493 P14499 P14507**

[27] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe [Brand: Yuflyma; Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only: Nil]**

(a) *omit from the column headed "Circumstances":* **C8638**

(b) *omit from the column headed "Circumstances":* **C11605**

(c) *omit from the column headed "Circumstances":* **C11720**

(d) *omit from the column headed "Circumstances":* **C11769 C11772**

(e) *omit from the column headed "Circumstances":* **C13550**

(f) *omit from the column headed "Circumstances":* **C13648**

(g) *omit from the column headed "Circumstances":* **C14058**

(h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

(i) *omit from the column headed "Purposes":* **P11605**

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- (j) *omit from the column headed "Purposes": P11720*
- (k) *omit from the column headed "Purposes": P11769 P11772*
- (l) *insert in numerical order in the column headed "Purposes": P14493 P14499 P14507 P14567*
- [28] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe [Brand: Humira; Maximum Quantity: 6; Number of Repeats: 0]**
- (a) *omit from the column headed "Circumstances": C8638*
- (b) *omit from the column headed "Circumstances": C11720*
- (c) *omit from the column headed "Circumstances": C11769 C11772*
- (d) *omit from the column headed "Circumstances": C13550*
- (e) *omit from the column headed "Circumstances": C13648*
- (f) *omit from the column headed "Circumstances": C14058*
- (g) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14498 C14499 C14507*
- [29] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe [Brand: Yuflyma; Maximum Quantity: 6; Number of Repeats: 0]**
- (a) *omit from the column headed "Circumstances": C8638*
- (b) *omit from the column headed "Circumstances": C11605*
- (c) *omit from the column headed "Circumstances": C11720*
- (d) *omit from the column headed "Circumstances": C11769 C11772*
- (e) *omit from the column headed "Circumstances": C13550*
- (f) *omit from the column headed "Circumstances": C13648*
- (g) *omit from the column headed "Circumstances": C14058*
- (h) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590*
- [30] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Amgevita; Maximum Quantity: 2; Number of Repeats: 0]**
- (a) *omit from the column headed "Circumstances": C8638*
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- (b) *omit from the column headed "Circumstances": C11605*
  - (c) *omit from the column headed "Circumstances": C11720*
  - (d) *omit from the column headed "Circumstances": C11769 C11772*
  - (e) *omit from the column headed "Circumstances": C13550*
  - (f) *omit from the column headed "Circumstances": C13648*
  - (g) *omit from the column headed "Circumstances": C14058*
  - (h) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590*

**[31] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Hadlima; Maximum Quantity: 2; Number of Repeats: 0]**

- (a) *omit from the column headed "Circumstances": C8638*
- (b) *omit from the column headed "Circumstances": C11605*
- (c) *omit from the column headed "Circumstances": C11720*
- (d) *omit from the column headed "Circumstances": C11769 C11772*
- (e) *omit from the column headed "Circumstances": C13550*
- (f) *omit from the column headed "Circumstances": C13648*
- (g) *omit from the column headed "Circumstances": C14058*
- (h) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590*

**[32] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Hyrimoz; Maximum Quantity: 2; Number of Repeats: 0]**

- (a) *omit from the column headed "Circumstances": C8638*
- (b) *omit from the column headed "Circumstances": C11605*
- (c) *omit from the column headed "Circumstances": C11720*
- (d) *omit from the column headed "Circumstances": C11769 C11772*
- (e) *omit from the column headed "Circumstances": C13550*

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- (f) omit from the column headed "Circumstances": **C13648**
  - (g) omit from the column headed "Circumstances": **C14058**
  - (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[33] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Idacio; Maximum Quantity: 2; Number of Repeats: 0]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**
- (d) omit from the column headed "Circumstances": **C11769 C11772**
- (e) omit from the column headed "Circumstances": **C13550**
- (f) omit from the column headed "Circumstances": **C13648**
- (g) omit from the column headed "Circumstances": **C14058**
- (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[34] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Amgevita; Maximum Quantity: 2; Number of Repeats: 2]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**
- (d) omit from the column headed "Circumstances": **C11769 C11772**
- (e) omit from the column headed "Circumstances": **C13550**
- (f) omit from the column headed "Circumstances": **C13648**
- (g) omit from the column headed "Circumstances": **C14058**
- (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

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- [35] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Hadlima; Maximum Quantity: 2; Number of Repeats: 2]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11605**
  - (c) *omit from the column headed "Circumstances":* **C11720**
  - (d) *omit from the column headed "Circumstances":* **C11769 C11772**
  - (e) *omit from the column headed "Circumstances":* **C13550**
  - (f) *omit from the column headed "Circumstances":* **C13648**
  - (g) *omit from the column headed "Circumstances":* **C14058**
  - (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
- [36] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Hyrimoz; Maximum Quantity: 2; Number of Repeats: 2]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11605**
  - (c) *omit from the column headed "Circumstances":* **C11720**
  - (d) *omit from the column headed "Circumstances":* **C11769 C11772**
  - (e) *omit from the column headed "Circumstances":* **C13550**
  - (f) *omit from the column headed "Circumstances":* **C13648**
  - (g) *omit from the column headed "Circumstances":* **C14058**
  - (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
- [37] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Idacio; Maximum Quantity: 2; Number of Repeats: 2]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11605**
  - (c) *omit from the column headed "Circumstances":* **C11720**
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- (d) omit from the column headed "Circumstances": **C11769 C11772**
  - (e) omit from the column headed "Circumstances": **C13550**
  - (f) omit from the column headed "Circumstances": **C13648**
  - (g) omit from the column headed "Circumstances": **C14058**
  - (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[38] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Amgevita; Maximum Quantity: 2; Number of Repeats: 3]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**
- (d) omit from the column headed "Circumstances": **C11769 C11772**
- (e) omit from the column headed "Circumstances": **C13550**
- (f) omit from the column headed "Circumstances": **C13648**
- (g) omit from the column headed "Circumstances": **C14058**
- (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
- (i) omit from the column headed "Purposes": **P8638**
- (j) omit from the column headed "Purposes": **P13550**
- (k) omit from the column headed "Purposes": **P13648**
- (l) omit from the column headed "Purposes": **P14058**
- (m) insert in numerical order in the column headed "Purposes": **P14483 P14486 P14488 P14496 P14498 P14568 P14590**

**[39] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Hadlima; Maximum Quantity: 2; Number of Repeats: 3]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**

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- (c) omit from the column headed "Circumstances": **C11720**
  - (d) omit from the column headed "Circumstances": **C11769 C11772**
  - (e) omit from the column headed "Circumstances": **C13550**
  - (f) omit from the column headed "Circumstances": **C13648**
  - (g) omit from the column headed "Circumstances": **C14058**
  - (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
  - (i) omit from the column headed "Purposes": **P8638**
  - (j) omit from the column headed "Purposes": **P13550**
  - (k) omit from the column headed "Purposes": **P13648**
  - (l) omit from the column headed "Purposes": **P14058**
  - (m) insert in numerical order in the column headed "Purposes": **P14483 P14486 P14488 P14496 P14498 P14568 P14590**

**[40] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Hyrimoz; Maximum Quantity: 2; Number of Repeats: 3]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**
- (d) omit from the column headed "Circumstances": **C11769 C11772**
- (e) omit from the column headed "Circumstances": **C13550**
- (f) omit from the column headed "Circumstances": **C13648**
- (g) omit from the column headed "Circumstances": **C14058**
- (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
- (i) omit from the column headed "Purposes": **P8638**
- (j) omit from the column headed "Purposes": **P13550**
- (k) omit from the column headed "Purposes": **P13648**

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- (l) omit from the column headed "Purposes": **P14058**
  - (m) insert in numerical order in the column headed "Purposes": **P14483 P14486 P14488 P14496 P14498 P14568 P14590**

**[41] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Idacio; Maximum Quantity: 2; Number of Repeats: 3]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**
- (d) omit from the column headed "Circumstances": **C11769 C11772**
- (e) omit from the column headed "Circumstances": **C13550**
- (f) omit from the column headed "Circumstances": **C13648**
- (g) omit from the column headed "Circumstances": **C14058**
- (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
- (i) omit from the column headed "Purposes": **P8638**
- (j) omit from the column headed "Purposes": **P13550**
- (k) omit from the column headed "Purposes": **P13648**
- (l) omit from the column headed "Purposes": **P14058**
- (m) insert in numerical order in the column headed "Purposes": **P14483 P14486 P14488 P14496 P14498 P14568 P14590**

**[42] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Amgevita; Maximum Quantity: 2; Number of Repeats: 4]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**
- (d) omit from the column headed "Circumstances": **C11769 C11772**
- (e) omit from the column headed "Circumstances": **C13550**
- (f) omit from the column headed "Circumstances": **C13648**

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- (g) *omit from the column headed "Circumstances":* **C14058**
  - (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[43] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Hadlima; Maximum Quantity: 2; Number of Repeats: 4]**

- (a) *omit from the column headed "Circumstances":* **C8638**
- (b) *omit from the column headed "Circumstances":* **C11605**
- (c) *omit from the column headed "Circumstances":* **C11720**
- (d) *omit from the column headed "Circumstances":* **C11769 C11772**
- (e) *omit from the column headed "Circumstances":* **C13550**
- (f) *omit from the column headed "Circumstances":* **C13648**
- (g) *omit from the column headed "Circumstances":* **C14058**
- (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[44] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Hyrimoz; Maximum Quantity: 2; Number of Repeats: 4]**

- (a) *omit from the column headed "Circumstances":* **C8638**
- (b) *omit from the column headed "Circumstances":* **C11605**
- (c) *omit from the column headed "Circumstances":* **C11720**
- (d) *omit from the column headed "Circumstances":* **C11769 C11772**
- (e) *omit from the column headed "Circumstances":* **C13550**
- (f) *omit from the column headed "Circumstances":* **C13648**
- (g) *omit from the column headed "Circumstances":* **C14058**
- (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

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- [45] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Idacio; Maximum Quantity: 2; Number of Repeats: 4]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11605**
  - (c) *omit from the column headed "Circumstances":* **C11720**
  - (d) *omit from the column headed "Circumstances":* **C11769 C11772**
  - (e) *omit from the column headed "Circumstances":* **C13550**
  - (f) *omit from the column headed "Circumstances":* **C13648**
  - (g) *omit from the column headed "Circumstances":* **C14058**
  - (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
- [46] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Amgevita; Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only: Nil]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11605**
  - (c) *omit from the column headed "Circumstances":* **C11720**
  - (d) *omit from the column headed "Circumstances":* **C11769 C11772**
  - (e) *omit from the column headed "Circumstances":* **C13550**
  - (f) *omit from the column headed "Circumstances":* **C13648**
  - (g) *omit from the column headed "Circumstances":* **C14058**
  - (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
  - (i) *omit from the column headed "Purposes":* **P11605**
  - (j) *omit from the column headed "Purposes":* **P11720**
  - (k) *omit from the column headed "Purposes":* **P11769 P11772**
  - (l) *insert in numerical order in the column headed "Purposes":* **P14493 P14499 P14507 P14567**
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- [47] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Hadlima; Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only: Nil]**
- (a) *omit from the column headed "Circumstances": C8638*
  - (b) *omit from the column headed "Circumstances": C11605*
  - (c) *omit from the column headed "Circumstances": C11720*
  - (d) *omit from the column headed "Circumstances": C11769 C11772*
  - (e) *omit from the column headed "Circumstances": C13550*
  - (f) *omit from the column headed "Circumstances": C13648*
  - (g) *omit from the column headed "Circumstances": C14058*
  - (h) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590*
  - (i) *omit from the column headed "Purposes": P11605*
  - (j) *omit from the column headed "Purposes": P11720*
  - (k) *omit from the column headed "Purposes": P11769 P11772*
  - (l) *insert in numerical order in the column headed "Purposes": P14493 P14499 P14507 P14567*
- [48] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Hyrimoz; Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only: Nil]**
- (a) *omit from the column headed "Circumstances": C8638*
  - (b) *omit from the column headed "Circumstances": C11605*
  - (c) *omit from the column headed "Circumstances": C11720*
  - (d) *omit from the column headed "Circumstances": C11769 C11772*
  - (e) *omit from the column headed "Circumstances": C13550*
  - (f) *omit from the column headed "Circumstances": C13648*
  - (g) *omit from the column headed "Circumstances": C14058*
  - (h) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590*
  - (i) *omit from the column headed "Purposes": P11605*
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- (j) omit from the column headed "Purposes": **P11720**
  - (k) omit from the column headed "Purposes": **P11769 P11772**
  - (l) insert in numerical order in the column headed "Purposes": **P14493 P14499 P14507 P14567**

**[49] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Idacio; Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only: Nil]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**
- (d) omit from the column headed "Circumstances": **C11769 C11772**
- (e) omit from the column headed "Circumstances": **C13550**
- (f) omit from the column headed "Circumstances": **C13648**
- (g) omit from the column headed "Circumstances": **C14058**
- (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
- (i) omit from the column headed "Purposes": **P11605**
- (j) omit from the column headed "Purposes": **P11720**
- (k) omit from the column headed "Purposes": **P11769 P11772**
- (l) insert in numerical order in the column headed "Purposes": **P14493 P14499 P14507 P14567**

**[50] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Amgevita; Maximum Quantity: 4; Number of Repeats: 2]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**
- (d) omit from the column headed "Circumstances": **C11769 C11772**
- (e) omit from the column headed "Circumstances": **C13550**
- (f) omit from the column headed "Circumstances": **C13648**

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- (g) *omit from the column headed "Circumstances":* **C14058**
  - (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[51] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Hadlima; Maximum Quantity: 4; Number of Repeats: 2]**

- (a) *omit from the column headed "Circumstances":* **C8638**
- (b) *omit from the column headed "Circumstances":* **C11605**
- (c) *omit from the column headed "Circumstances":* **C11720**
- (d) *omit from the column headed "Circumstances":* **C11769 C11772**
- (e) *omit from the column headed "Circumstances":* **C13550**
- (f) *omit from the column headed "Circumstances":* **C13648**
- (g) *omit from the column headed "Circumstances":* **C14058**
- (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[52] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Hyrimoz; Maximum Quantity: 4; Number of Repeats: 2]**

- (a) *omit from the column headed "Circumstances":* **C8638**
- (b) *omit from the column headed "Circumstances":* **C11605**
- (c) *omit from the column headed "Circumstances":* **C11720**
- (d) *omit from the column headed "Circumstances":* **C11769 C11772**
- (e) *omit from the column headed "Circumstances":* **C13550**
- (f) *omit from the column headed "Circumstances":* **C13648**
- (g) *omit from the column headed "Circumstances":* **C14058**
- (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

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- [53] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Idacio; Maximum Quantity: 4; Number of Repeats: 2]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11605**
  - (c) *omit from the column headed "Circumstances":* **C11720**
  - (d) *omit from the column headed "Circumstances":* **C11769 C11772**
  - (e) *omit from the column headed "Circumstances":* **C13550**
  - (f) *omit from the column headed "Circumstances":* **C13648**
  - (g) *omit from the column headed "Circumstances":* **C14058**
  - (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
- [54] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Amgevita; Maximum Quantity: 4; Number of Repeats: 5]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11605**
  - (c) *omit from the column headed "Circumstances":* **C11720**
  - (d) *omit from the column headed "Circumstances":* **C11769 C11772**
  - (e) *omit from the column headed "Circumstances":* **C13550**
  - (f) *omit from the column headed "Circumstances":* **C13648**
  - (g) *omit from the column headed "Circumstances":* **C14058**
  - (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
- [55] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Hadlima; Maximum Quantity: 4; Number of Repeats: 5]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11605**
  - (c) *omit from the column headed "Circumstances":* **C11720**
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- (d) omit from the column headed "Circumstances": **C11769 C11772**
  - (e) omit from the column headed "Circumstances": **C13550**
  - (f) omit from the column headed "Circumstances": **C13648**
  - (g) omit from the column headed "Circumstances": **C14058**
  - (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[56] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Hyrimoz; Maximum Quantity: 4; Number of Repeats: 5]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**
- (d) omit from the column headed "Circumstances": **C11769 C11772**
- (e) omit from the column headed "Circumstances": **C13550**
- (f) omit from the column headed "Circumstances": **C13648**
- (g) omit from the column headed "Circumstances": **C14058**
- (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[57] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Idacio; Maximum Quantity: 4; Number of Repeats: 5]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**
- (d) omit from the column headed "Circumstances": **C11769 C11772**
- (e) omit from the column headed "Circumstances": **C13550**
- (f) omit from the column headed "Circumstances": **C13648**
- (g) omit from the column headed "Circumstances": **C14058**

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(h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[58] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Amgevita; Maximum Quantity: 6; Number of Repeats: 0]**

(a) *omit from the column headed "Circumstances":* **C8638**

(b) *omit from the column headed "Circumstances":* **C11605**

(c) *omit from the column headed "Circumstances":* **C11720**

(d) *omit from the column headed "Circumstances":* **C11769 C11772**

(e) *omit from the column headed "Circumstances":* **C13550**

(f) *omit from the column headed "Circumstances":* **C13648**

(g) *omit from the column headed "Circumstances":* **C14058**

(h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[59] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Hadlima; Maximum Quantity: 6; Number of Repeats: 0]**

(a) *omit from the column headed "Circumstances":* **C8638**

(b) *omit from the column headed "Circumstances":* **C11605**

(c) *omit from the column headed "Circumstances":* **C11720**

(d) *omit from the column headed "Circumstances":* **C11769 C11772**

(e) *omit from the column headed "Circumstances":* **C13550**

(f) *omit from the column headed "Circumstances":* **C13648**

(g) *omit from the column headed "Circumstances":* **C14058**

(h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[60] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Hyrimoz; Maximum Quantity: 6; Number of Repeats: 0]**

(a) *omit from the column headed "Circumstances":* **C8638**

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- (b) *omit from the column headed "Circumstances": C11605*
  - (c) *omit from the column headed "Circumstances": C11720*
  - (d) *omit from the column headed "Circumstances": C11769 C11772*
  - (e) *omit from the column headed "Circumstances": C13550*
  - (f) *omit from the column headed "Circumstances": C13648*
  - (g) *omit from the column headed "Circumstances": C14058*
  - (h) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590*

**[61] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen [Brand: Idacio; Maximum Quantity: 6; Number of Repeats: 0]**

- (a) *omit from the column headed "Circumstances": C8638*
- (b) *omit from the column headed "Circumstances": C11605*
- (c) *omit from the column headed "Circumstances": C11720*
- (d) *omit from the column headed "Circumstances": C11769 C11772*
- (e) *omit from the column headed "Circumstances": C13550*
- (f) *omit from the column headed "Circumstances": C13648*
- (g) *omit from the column headed "Circumstances": C14058*
- (h) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590*

**[62] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Amgevita; Maximum Quantity: 2; Number of Repeats: 0]**

- (a) *omit from the column headed "Circumstances": C8638*
- (b) *omit from the column headed "Circumstances": C11605*
- (c) *omit from the column headed "Circumstances": C11720*
- (d) *omit from the column headed "Circumstances": C11769 C11772*
- (e) *omit from the column headed "Circumstances": C13550*

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- (f) omit from the column headed "Circumstances": **C13648**
  - (g) omit from the column headed "Circumstances": **C14058**
  - (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[63] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Hadlima; Maximum Quantity: 2; Number of Repeats: 0]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**
- (d) omit from the column headed "Circumstances": **C11769 C11772**
- (e) omit from the column headed "Circumstances": **C13550**
- (f) omit from the column headed "Circumstances": **C13648**
- (g) omit from the column headed "Circumstances": **C14058**
- (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[64] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Hyrimoz; Maximum Quantity: 2; Number of Repeats: 0]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**
- (d) omit from the column headed "Circumstances": **C11769 C11772**
- (e) omit from the column headed "Circumstances": **C13550**
- (f) omit from the column headed "Circumstances": **C13648**
- (g) omit from the column headed "Circumstances": **C14058**
- (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**



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- [65] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Idacio; Maximum Quantity: 2; Number of Repeats: 0]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11605**
  - (c) *omit from the column headed "Circumstances":* **C11720**
  - (d) *omit from the column headed "Circumstances":* **C11769 C11772**
  - (e) *omit from the column headed "Circumstances":* **C13550**
  - (f) *omit from the column headed "Circumstances":* **C13648**
  - (g) *omit from the column headed "Circumstances":* **C14058**
  - (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
- [66] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Amgevita; Maximum Quantity: 2; Number of Repeats: 2]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11605**
  - (c) *omit from the column headed "Circumstances":* **C11720**
  - (d) *omit from the column headed "Circumstances":* **C11769 C11772**
  - (e) *omit from the column headed "Circumstances":* **C13550**
  - (f) *omit from the column headed "Circumstances":* **C13648**
  - (g) *omit from the column headed "Circumstances":* **C14058**
  - (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
- [67] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Hadlima; Maximum Quantity: 2; Number of Repeats: 2]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11605**
  - (c) *omit from the column headed "Circumstances":* **C11720**
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- (d) omit from the column headed "Circumstances": **C11769 C11772**
  - (e) omit from the column headed "Circumstances": **C13550**
  - (f) omit from the column headed "Circumstances": **C13648**
  - (g) omit from the column headed "Circumstances": **C14058**
  - (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[68] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Hyrimoz; Maximum Quantity: 2; Number of Repeats: 2]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**
- (d) omit from the column headed "Circumstances": **C11769 C11772**
- (e) omit from the column headed "Circumstances": **C13550**
- (f) omit from the column headed "Circumstances": **C13648**
- (g) omit from the column headed "Circumstances": **C14058**
- (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[69] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Idacio; Maximum Quantity: 2; Number of Repeats: 2]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**
- (d) omit from the column headed "Circumstances": **C11769 C11772**
- (e) omit from the column headed "Circumstances": **C13550**
- (f) omit from the column headed "Circumstances": **C13648**
- (g) omit from the column headed "Circumstances": **C14058**

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(h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[70] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Amgevita; Maximum Quantity: 2; Number of Repeats: 3]**

(a) *omit from the column headed "Circumstances":* **C8638**

(b) *omit from the column headed "Circumstances":* **C11605**

(c) *omit from the column headed "Circumstances":* **C11720**

(d) *omit from the column headed "Circumstances":* **C11769 C11772**

(e) *omit from the column headed "Circumstances":* **C13550**

(f) *omit from the column headed "Circumstances":* **C13648**

(g) *omit from the column headed "Circumstances":* **C14058**

(h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

(i) *omit from the column headed "Purposes":* **P8638**

(j) *omit from the column headed "Purposes":* **P13550**

(k) *omit from the column headed "Purposes":* **P13648**

(l) *omit from the column headed "Purposes":* **P14058**

(m) *insert in numerical order in the column headed "Purposes":* **P14483 P14486 P14488 P14496 P14498 P14568 P14590**

**[71] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Hadlima; Maximum Quantity: 2; Number of Repeats: 3]**

(a) *omit from the column headed "Circumstances":* **C8638**

(b) *omit from the column headed "Circumstances":* **C11605**

(c) *omit from the column headed "Circumstances":* **C11720**

(d) *omit from the column headed "Circumstances":* **C11769 C11772**

(e) *omit from the column headed "Circumstances":* **C13550**

(f) *omit from the column headed "Circumstances":* **C13648**

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- (g) *omit from the column headed "Circumstances":* **C14058**
  - (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
  - (i) *omit from the column headed "Purposes":* **P8638**
  - (j) *omit from the column headed "Purposes":* **P13550**
  - (k) *omit from the column headed "Purposes":* **P13648**
  - (l) *omit from the column headed "Purposes":* **P14058**
  - (m) *insert in numerical order in the column headed "Purposes":* **P14483 P14486 P14488 P14496 P14498 P14568 P14590**

**[72] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Hyrimoz; Maximum Quantity: 2; Number of Repeats: 3]**

- (a) *omit from the column headed "Circumstances":* **C8638**
- (b) *omit from the column headed "Circumstances":* **C11605**
- (c) *omit from the column headed "Circumstances":* **C11720**
- (d) *omit from the column headed "Circumstances":* **C11769 C11772**
- (e) *omit from the column headed "Circumstances":* **C13550**
- (f) *omit from the column headed "Circumstances":* **C13648**
- (g) *omit from the column headed "Circumstances":* **C14058**
- (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
- (i) *omit from the column headed "Purposes":* **P8638**
- (j) *omit from the column headed "Purposes":* **P13550**
- (k) *omit from the column headed "Purposes":* **P13648**
- (l) *omit from the column headed "Purposes":* **P14058**
- (m) *insert in numerical order in the column headed "Purposes":* **P14483 P14486 P14488 P14496 P14498 P14568 P14590**

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[73] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Idacio; Maximum Quantity: 2; Number of Repeats: 3]**

- (a) *omit from the column headed "Circumstances":* **C8638**
- (b) *omit from the column headed "Circumstances":* **C11605**
- (c) *omit from the column headed "Circumstances":* **C11720**
- (d) *omit from the column headed "Circumstances":* **C11769 C11772**
- (e) *omit from the column headed "Circumstances":* **C13550**
- (f) *omit from the column headed "Circumstances":* **C13648**
- (g) *omit from the column headed "Circumstances":* **C14058**
- (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
- (i) *omit from the column headed "Purposes":* **P8638**
- (j) *omit from the column headed "Purposes":* **P13550**
- (k) *omit from the column headed "Purposes":* **P13648**
- (l) *omit from the column headed "Purposes":* **P14058**
- (m) *insert in numerical order in the column headed "Purposes":* **P14483 P14486 P14488 P14496 P14498 P14568 P14590**

[74] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Amgevita; Maximum Quantity: 2; Number of Repeats: 4]**

- (a) *omit from the column headed "Circumstances":* **C8638**
- (b) *omit from the column headed "Circumstances":* **C11605**
- (c) *omit from the column headed "Circumstances":* **C11720**
- (d) *omit from the column headed "Circumstances":* **C11769 C11772**
- (e) *omit from the column headed "Circumstances":* **C13550**
- (f) *omit from the column headed "Circumstances":* **C13648**
- (g) *omit from the column headed "Circumstances":* **C14058**
- (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

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- [75] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Hadlima; Maximum Quantity: 2; Number of Repeats: 4]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11605**
  - (c) *omit from the column headed "Circumstances":* **C11720**
  - (d) *omit from the column headed "Circumstances":* **C11769 C11772**
  - (e) *omit from the column headed "Circumstances":* **C13550**
  - (f) *omit from the column headed "Circumstances":* **C13648**
  - (g) *omit from the column headed "Circumstances":* **C14058**
  - (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
- [76] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Hyrimoz; Maximum Quantity: 2; Number of Repeats: 4]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11605**
  - (c) *omit from the column headed "Circumstances":* **C11720**
  - (d) *omit from the column headed "Circumstances":* **C11769 C11772**
  - (e) *omit from the column headed "Circumstances":* **C13550**
  - (f) *omit from the column headed "Circumstances":* **C13648**
  - (g) *omit from the column headed "Circumstances":* **C14058**
  - (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
- [77] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Idacio; Maximum Quantity: 2; Number of Repeats: 4]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11605**
  - (c) *omit from the column headed "Circumstances":* **C11720**
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- (d) omit from the column headed "Circumstances": **C11769 C11772**
  - (e) omit from the column headed "Circumstances": **C13550**
  - (f) omit from the column headed "Circumstances": **C13648**
  - (g) omit from the column headed "Circumstances": **C14058**
  - (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[78] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Amgevita; Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only: Nil]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**
- (d) omit from the column headed "Circumstances": **C11769 C11772**
- (e) omit from the column headed "Circumstances": **C13550**
- (f) omit from the column headed "Circumstances": **C13648**
- (g) omit from the column headed "Circumstances": **C14058**
- (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
- (i) omit from the column headed "Purposes": **P11605**
- (j) omit from the column headed "Purposes": **P11720**
- (k) omit from the column headed "Purposes": **P11769 P11772**
- (l) insert in numerical order in the column headed "Purposes": **P14493 P14499 P14507 P14567**

**[79] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Hadlima; Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only: Nil]**

- (a) omit from the column headed "Circumstances": **C8638**
- (b) omit from the column headed "Circumstances": **C11605**
- (c) omit from the column headed "Circumstances": **C11720**

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- (d) *omit from the column headed "Circumstances": C11769 C11772*
  - (e) *omit from the column headed "Circumstances": C13550*
  - (f) *omit from the column headed "Circumstances": C13648*
  - (g) *omit from the column headed "Circumstances": C14058*
  - (h) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590*
  - (i) *omit from the column headed "Purposes": P11605*
  - (j) *omit from the column headed "Purposes": P11720*
  - (k) *omit from the column headed "Purposes": P11769 P11772*
  - (l) *insert in numerical order in the column headed "Purposes": P14493 P14499 P14507 P14567*

**[80] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Hyrimoz; Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only: Nil]**

- (a) *omit from the column headed "Circumstances": C8638*
- (b) *omit from the column headed "Circumstances": C11605*
- (c) *omit from the column headed "Circumstances": C11720*
- (d) *omit from the column headed "Circumstances": C11769 C11772*
- (e) *omit from the column headed "Circumstances": C13550*
- (f) *omit from the column headed "Circumstances": C13648*
- (g) *omit from the column headed "Circumstances": C14058*
- (h) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590*
- (i) *omit from the column headed "Purposes": P11605*
- (j) *omit from the column headed "Purposes": P11720*
- (k) *omit from the column headed "Purposes": P11769 P11772*
- (l) *insert in numerical order in the column headed "Purposes": P14493 P14499 P14507 P14567*



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- [81] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Idacio; Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only: Nil]**
- (a) *omit from the column headed "Circumstances": C8638*
  - (b) *omit from the column headed "Circumstances": C11605*
  - (c) *omit from the column headed "Circumstances": C11720*
  - (d) *omit from the column headed "Circumstances": C11769 C11772*
  - (e) *omit from the column headed "Circumstances": C13550*
  - (f) *omit from the column headed "Circumstances": C13648*
  - (g) *omit from the column headed "Circumstances": C14058*
  - (h) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590*
  - (i) *omit from the column headed "Purposes": P11605*
  - (j) *omit from the column headed "Purposes": P11720*
  - (k) *omit from the column headed "Purposes": P11769 P11772*
  - (l) *insert in numerical order in the column headed "Purposes": P14493 P14499 P14507 P14567*
- [82] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Amgevita; Maximum Quantity: 6; Number of Repeats: 0]**
- (a) *omit from the column headed "Circumstances": C8638*
  - (b) *omit from the column headed "Circumstances": C11605*
  - (c) *omit from the column headed "Circumstances": C11720*
  - (d) *omit from the column headed "Circumstances": C11769 C11772*
  - (e) *omit from the column headed "Circumstances": C13550*
  - (f) *omit from the column headed "Circumstances": C13648*
  - (g) *omit from the column headed "Circumstances": C14058*
  - (h) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590*
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- [83] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Hadlima; Maximum Quantity: 6; Number of Repeats: 0]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11605**
  - (c) *omit from the column headed "Circumstances":* **C11720**
  - (d) *omit from the column headed "Circumstances":* **C11769 C11772**
  - (e) *omit from the column headed "Circumstances":* **C13550**
  - (f) *omit from the column headed "Circumstances":* **C13648**
  - (g) *omit from the column headed "Circumstances":* **C14058**
  - (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
- [84] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Hyrimoz; Maximum Quantity: 6; Number of Repeats: 0]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11605**
  - (c) *omit from the column headed "Circumstances":* **C11720**
  - (d) *omit from the column headed "Circumstances":* **C11769 C11772**
  - (e) *omit from the column headed "Circumstances":* **C13550**
  - (f) *omit from the column headed "Circumstances":* **C13648**
  - (g) *omit from the column headed "Circumstances":* **C14058**
  - (h) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**
- [85] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe [Brand: Idacio; Maximum Quantity: 6; Number of Repeats: 0]**
- (a) *omit from the column headed "Circumstances":* **C8638**
  - (b) *omit from the column headed "Circumstances":* **C11605**
  - (c) *omit from the column headed "Circumstances":* **C11720**
-

- (d) omit from the column headed "Circumstances": **C11769 C11772**
- (e) omit from the column headed "Circumstances": **C13550**
- (f) omit from the column headed "Circumstances": **C13648**
- (g) omit from the column headed "Circumstances": **C14058**
- (h) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590**

**[86] Schedule 1, Part 1, entry for Amlodipine with valsartan**

*substitute:*

Amlodipine with valsartan	Tablet 5 mg (as besilate)-80 mg	Oral	a	Amlodipine/Valsartan Novartis 5/80	NM	MP NP	C4373 C14257	P4373	28	5	28
			a	Exforge 5/80	NV	MP NP	C4373 C14257	P4373	28	5	28
			a	Amlodipine/Valsartan Novartis 5/80	NM	MP NP	C4373 C14257	P14257	56	5	28
			a	Exforge 5/80	NV	MP NP	C4373 C14257	P14257	56	5	28
	Tablet 5 mg (as besilate)-160 mg	Oral	a	Amlodipine/Valsartan Novartis 5/160	NM	MP NP	C4373 C14257	P4373	28	5	28
			a	Exforge 5/160	NV	MP NP	C4373 C14257	P4373	28	5	28
			a	Amlodipine/Valsartan Novartis 5/160	NM	MP NP	C4373 C14257	P14257	56	5	28
			a	Exforge 5/160	NV	MP NP	C4373 C14257	P14257	56	5	28
	Tablet 5 mg (as besilate)-320 mg	Oral	a	Amlodipine/Valsartan Novartis 5/320	NM	MP NP	C4373 C14257	P4373	28	5	28
			a	Exforge 5/320	NV	MP NP	C4373 C14257	P4373	28	5	28
			a	Amlodipine/Valsartan Novartis 5/320	NM	MP NP	C4373 C14257	P14257	56	5	28
			a	Exforge 5/320	NV	MP NP	C4373 C14257	P14257	56	5	28

Tablet 10 mg (as besilate)- 160 mg	Oral	a	Amlodipine/Valsartan Novartis 10/160	NM	MP NP	C4373 C14257	P4373	28	5	28
		a	Exforge 10/160	NV	MP NP	C4373 C14257	P4373	28	5	28
		a	Amlodipine/Valsartan Novartis 10/160	NM	MP NP	C4373 C14257	P14257	56	5	28
		a	Exforge 10/160	NV	MP NP	C4373 C14257	P14257	56	5	28
Tablet 10 mg (as besilate)- 320 mg	Oral	a	Amlodipine/Valsartan Novartis 10/320	NM	MP NP	C4373 C14257	P4373	28	5	28
		a	Exforge 10/320	NV	MP NP	C4373 C14257	P4373	28	5	28
		a	Amlodipine/Valsartan Novartis 10/320	NM	MP NP	C4373 C14257	P14257	56	5	28
		a	Exforge 10/320	NV	MP NP	C4373 C14257	P14257	56	5	28

**[87] Schedule 1, Part 1, entry for Amlodipine with valsartan and hydrochlorothiazide**

*substitute:*

Amlodipine with valsartan and hydrochlorothiazide	Tablet 5 mg (as besilate)- 160 mg-12.5 mg	Oral	a	Amlodipine/Valsartan/HCT Novartis 5/160/12.5	NM	MP NP	C4311 C14272	P4311	28	5	28
			a	Exforge HCT 5/160/12.5	NV	MP NP	C4311 C14272	P4311	28	5	28
			a	Amlodipine/Valsartan/HCT Novartis 5/160/12.5	NM	MP NP	C4311 C14272	P14272	56	5	28
			a	Exforge HCT 5/160/12.5	NV	MP NP	C4311 C14272	P14272	56	5	28
Tablet 5 mg (as besilate)- 160 mg-25 mg	Oral	a	Amlodipine/Valsartan/HCT Novartis 5/160/25	NM	MP NP	C4311 C14272	P4311	28	5	28	
		a	Exforge HCT 5/160/25	NV	MP NP	C4311 C14272	P4311	28	5	28	

		a	Amlodipine/Valsartan/HCT Novartis 5/160/25	NM	MP NP	C4311 C14272	P14272	56	5	28
		a	Exforge HCT 5/160/25	NV	MP NP	C4311 C14272	P14272	56	5	28
Tablet 10 mg (as besilate)- 160 mg-12.5 mg	Oral	a	Amlodipine/Valsartan/HCT Novartis 10/160/12.5	NM	MP NP	C4311 C14272	P4311	28	5	28
		a	Exforge HCT 10/160/12.5	NV	MP NP	C4311 C14272	P4311	28	5	28
		a	Amlodipine/Valsartan/HCT Novartis 10/160/12.5	NM	MP NP	C4311 C14272	P14272	56	5	28
		a	Exforge HCT 10/160/12.5	NV	MP NP	C4311 C14272	P14272	56	5	28
Tablet 10 mg (as besilate)- 160 mg-25 mg	Oral	a	Amlodipine/Valsartan/HCT Novartis 10/160/25	NM	MP NP	C4311 C14272	P4311	28	5	28
		a	Exforge HCT 10/160/25	NV	MP NP	C4311 C14272	P4311	28	5	28
		a	Amlodipine/Valsartan/HCT Novartis 10/160/25	NM	MP NP	C4311 C14272	P14272	56	5	28
		a	Exforge HCT 10/160/25	NV	MP NP	C4311 C14272	P14272	56	5	28
Tablet 10 mg (as besilate)- 320 mg-25 mg	Oral	a	Amlodipine/Valsartan/HCT Novartis 10/320/25	NM	MP NP	C4311 C14272	P4311	28	5	28
		a	Exforge HCT 10/320/25	NV	MP NP	C4311 C14272	P4311	28	5	28
		a	Amlodipine/Valsartan/HCT Novartis	NM	MP NP	C4311 C14272	P14272	56	5	28

			10/320/25							
a	Exforge HCT 10/320/25	NV	MP NP	C4311 C14272	P14272		56	5	28	

**[88] Schedule 1, Part 1, after entry for Amoxicillin with clavulanic acid in the form Powder for oral suspension containing 125 mg amoxicillin (as trihydrate) with 31.25 mg clavulanic acid (as potassium clavulanate) per 5 mL, 75 mL**

*insert:*

	Powder for oral suspension containing 400 mg amoxicillin (as trihydrate) with 57 mg clavulanic acid (as potassium clavulanate) per 5 mL, 50 mL (S19A)	Oral	Amoxicillin and clavulanate potassium for oral suspension, USP 400 mg/57 mg per 5 mL (Aurobindo)	DZ	PDP	C5833 C5894		1	0	1
					MP NP	C5832 C5893		1	1	1

**[89] Schedule 1, Part 1, entry for Amoxicillin with clavulanic acid in the form Powder for oral suspension containing 400 mg amoxicillin (as trihydrate) with 57 mg clavulanic acid (as potassium clavulanate) per 5 mL, 60 mL**

*omit from the column headed "Schedule Equivalent" (all instances): a*

**[90] Schedule 1, Part 1, entry for Amoxicillin with clavulanic acid in the form Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)**

**(a)** *omit:*

a	Alphaclav Duo Viatriis	AL	MP NP	C5832 C5893 C10405	P5832 P5893		10	0	10
			MW	C5832 C5893			10	0	10
			PDP	C5833 C5894			10	0	10

**(b)** *omit:*

a	Alphaclav Duo Viatriis	AL	MP NP	C5832 C5893 C10405	P10405		20	0	10
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**[91] Schedule 1, Part 1, entry for Atorvastatin in the form Tablet 10 mg (as calcium) [Maximum Quantity: 30; Number of Repeats: 5]**

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

a	BTC Atorvastatin	BG	MP NP		30	5	30
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**[92] Schedule 1, Part 1, entry for Atorvastatin in the form Tablet 10 mg (as calcium) [Maximum Quantity: 60; Number of Repeats: 5]**

**(a)** omit from the column headed "Authorised Prescriber" (all instances): **MP** substitute (all instances): **MP NP**

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

a	BTC Atorvastatin	BG	MP NP	P14238	60	5	30
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**[93] Schedule 1, Part 1, entry for Atorvastatin in the form Tablet 20 mg (as calcium) [Maximum Quantity: 30; Number of Repeats: 5]**

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

a	BTC Atorvastatin	BG	MP NP		30	5	30
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**[94] Schedule 1, Part 1, entry for Atorvastatin in the form Tablet 20 mg (as calcium) [Maximum Quantity: 60; Number of Repeats: 5]**

**(a)** omit from the column headed "Authorised Prescriber" (all instances): **MP** substitute (all instances): **MP NP**

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

a	BTC Atorvastatin	BG	MP NP	P14238	60	5	30
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**[95] Schedule 1, Part 1, entry for Atorvastatin in the form Tablet 40 mg (as calcium) [Maximum Quantity: 30; Number of Repeats: 5]**

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

a	BTC Atorvastatin	BG	MP NP		30	5	30
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**[96] Schedule 1, Part 1, entry for Atorvastatin in the form Tablet 40 mg (as calcium) [Maximum Quantity: 60; Number of Repeats: 5]**

**(a)** omit from the column headed "Authorised Prescriber" (all instances): **MP** substitute (all instances): **MP NP**

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

a	BTC Atorvastatin	BG	MP NP	P14238	60	5	30
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**[97] Schedule 1, Part 1, entry for Atorvastatin in the form Tablet 80 mg (as calcium) [Maximum Quantity: 30; Number of Repeats: 5]**

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

a	BTC Atorvastatin	BG	MP NP		30	5	30
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**[98] Schedule 1, Part 1, entry for Atorvastatin in the form Tablet 80 mg (as calcium) [Maximum Quantity: 60; Number of Repeats: 5]**

**(a)** omit from the column headed "Authorised Prescriber" (all instances): **MP** substitute (all instances): **MP NP**

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

a	BTC Atorvastatin	BG	MP NP	P14238	60	5	30
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**[99] Schedule 1, Part 1, entry for Atropine in the form Injection containing atropine sulfate monohydrate 600 micrograms in 1 mL**

**(a)** omit from the column headed "Brand": **Pfizer Australia Pty Ltd** substitute: **Atropine Injection (Pfizer)**

**(b)** omit from the column headed "Responsible Person": **PF** substitute: **WZ**

**[100] Schedule 1, Part 1, entry for Baricitinib**

substitute:

Baricitinib	Tablet 2 mg	Oral	Olumiant	LY	MP	C14483 C14486 P14483 P14486	28	3	28
						C14488 C14493 P14488 P14498 C14498 C14499 C14507			
					MP	C14483 C14486 P14493 P14499	28	5	28
						C14488 C14493 P14507 C14498 C14499 C14507			
	Tablet 4 mg	Oral	Olumiant	LY	MP	C14483 C14486 P14483 P14486	28	3	28
						C14488 C14493 P14488 P14498 C14498 C14499 C14507			
					MP	C14483 C14486 P14493 P14499	28	5	28
						C14488 C14493 P14507 C14498 C14499 C14507			

**[101] Schedule 1, Part 1, entry for Blinatumomab**

**(a)** omit from the column headed "Circumstances": **C9911 C9936 C9937**

**(b)** insert in numerical order in the column headed "Circumstances": **C14587 C14588 C14631**



**[102] Schedule 1, Part 1, entry for Bortezomib in the form Powder for injection 1 mg**

*omit:*

						Bortezomib Juno	JU	MP	C11099 C13745		See Note 3	See Note 3	1	D(100)
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**[103] Schedule 1, Part 1, entry for Budesonide in the form Tablet 500 micrograms (orally disintegrating)**

*substitute:*

	Tablet 500 micrograms (orally disintegrating)	Oral	Jorveza	FD	MP	C14610 C14619	P14619	60	5	60
					MP	C14610 C14619	P14610	60	8	60

**[104] Schedule 1, Part 1, entry for Budesonide in the form Tablet 1 mg (orally disintegrating)**

*substitute:*

	Tablet 1 mg (orally disintegrating)	Oral	Jorveza	FD	MP	C14608 C14610	P14619	60	5	60
					MP	C14608 C14610	P14610	60	8	60
					MP	C14608 C14610	P14608	90	1	90

**[105] 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**

*omit from the column headed "Responsible Person" for the brand "Rilast TURBUHALER 200/6" (all instances): ZA* *substitute: XT*

**[106] 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**

*omit from the column headed "Responsible Person" for the brand "Rilast TURBUHALER 400/12": ZA* *substitute: XT*

**[107] Schedule 1, Part 1, entry for Budesonide with formoterol in the form Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses**

*omit from the column headed "Responsible Person" for the brand "Rilast RAPIHALER 100/3" (all instances): ZA* *substitute: XT*

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[108] **Schedule 1, Part 1, entry for Budesonide with formoterol in the form Pressurised inhalation containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses**

*omit from the column headed "Responsible Person" for the brand "Rilast RAPIHALER 200/6":* **ZA** *substitute:* **XT**

[109] **Schedule 1, Part 1, entry for Carbimazole**

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

a	THIRAZOL	NB	MP	NP	200	2	100
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[110] **Schedule 1, Part 1, entry for Carmellose in the form Eye drops containing carmellose sodium 5 mg per mL, single dose units 0.4 mL, 30**

(a) *omit from the column headed "Schedule Equivalent" for the brand "Cellufresh":* **a**

(b) *omit:*

a	Optifresh Tears	PP	MP	NP	AO	C6172	3	5	1
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[111] **Schedule 1, Part 1, entry for Carmellose in the form Eye drops containing carmellose sodium 10 mg per mL, single dose units 0.4 mL, 30**

(a) *omit from the column headed "Schedule Equivalent" for the brand "Celluvisc":* **a**

(b) *omit:*

a	Optifresh Plus	PP	MP	NP	AO	C6172	3	5	1
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[112] **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":* **C8627 C8679 C8706**

(b) *omit from the column headed "Circumstances":* **C11686 C11748**

(c) *omit from the column headed "Circumstances":* **C14113**

(d) *insert in numerical order in the column headed "Circumstances":* **C14493 C14499 C14507 C14542 C14571 C14591 C14622**

[113] **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":* **C8627 C8679 C8706**

(b) *omit from the column headed "Circumstances":* **C11686 C11748**

- 
- (c) *omit from the column headed "Circumstances": C14113*
- (d) *insert in numerical order in the column headed "Circumstances": C14493 C14499 C14507 C14542 C14571 C14591 C14622*
- (e) *omit from the column headed "Purposes": P8706*
- (f) *insert in numerical order in the column headed "Purposes": P14542*
- [114] 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": C8627 C8679 C8706*
- (b) *omit from the column headed "Circumstances": C11686 C11748*
- (c) *omit from the column headed "Circumstances": C14113*
- (d) *insert in numerical order in the column headed "Circumstances": C14493 C14499 C14507 C14542 C14571 C14591 C14622*
- (e) *omit from the column headed "Purposes": P8627 P8679*
- (f) *insert in numerical order in the column headed "Purposes": P14493 P14499 P14507*
- [115] 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": C8627 C8679 C8706*
- (b) *omit from the column headed "Circumstances": C11686 C11748*
- (c) *omit from the column headed "Circumstances": C14113*
- (d) *insert in numerical order in the column headed "Circumstances": C14493 C14499 C14507 C14542 C14571 C14591 C14622*
- (e) *omit from the column headed "Purposes": P11686 P11748 P14113*
- (f) *insert in numerical order in the column headed "Purposes": P14571 P14591 P14622*
- [116] 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": C8627 C8679 C8706*
- (b) *omit from the column headed "Circumstances": C11686 C11748*
- (c) *omit from the column headed "Circumstances": C14113*
- (d) *insert in numerical order in the column headed "Circumstances": C14493 C14499 C14507 C14542 C14571 C14591 C14622*
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- [117] **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":* **C8627 C8679 C8706**
  - (b) *omit from the column headed "Circumstances":* **C11686 C11748**
  - (c) *omit from the column headed "Circumstances":* **C14113**
  - (d) *insert in numerical order in the column headed "Circumstances":* **C14493 C14499 C14507 C14542 C14571 C14591 C14622**
  - (e) *omit from the column headed "Purposes":* **P8706**
  - (f) *insert in numerical order in the column headed "Purposes":* **P14542**
- [118] **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":* **C8627 C8679 C8706**
  - (b) *omit from the column headed "Circumstances":* **C11686 C11748**
  - (c) *omit from the column headed "Circumstances":* **C14113**
  - (d) *insert in numerical order in the column headed "Circumstances":* **C14493 C14499 C14507 C14542 C14571 C14591 C14622**
  - (e) *omit from the column headed "Purposes":* **P8627 P8679**
  - (f) *insert in numerical order in the column headed "Purposes":* **P14493 P14499 P14507**
- [119] **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":* **C8627 C8679 C8706**
  - (b) *omit from the column headed "Circumstances":* **C11686 C11748**
  - (c) *omit from the column headed "Circumstances":* **C14113**
  - (d) *insert in numerical order in the column headed "Circumstances":* **C14493 C14499 C14507 C14542 C14571 C14591 C14622**
  - (e) *omit from the column headed "Purposes":* **P11686 P11748 P14113**
  - (f) *insert in numerical order in the column headed "Purposes":* **P14571 P14591 P14622**
- [120] **Schedule 1, Part 1, entry for Clopidogrel with aspirin**
- (a) *omit:*
-

			a	CLOPIDOGREL/AS ED PIRIN AN 75/100	MP NP		30	5	30
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(b) omit:

			a	CLOPIDOGREL/AS ED PIRIN AN 75/100	MP NP	P14238	60	5	30
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**[121] Schedule 1, Part 1, entry for Empagliflozin in the form Tablet 10 mg**

insert in numerical order in the column headed "Circumstances" (all instances): **C14471**

**[122] Schedule 1, Part 1, entry for Enoxaparin**

substitute:

Enoxaparin	Injection containing enoxaparin sodium 20 mg (2,000 I.U. anti-Xa) in 0.2 mL pre-filled syringe	Injection	a	Clexane Safety-Lock	AV	MP NP		20	1	10
			a	Exarane	JU	MP NP		20	1	10
			a	Clexane Safety-Lock	AV	MP NP	P4910	20	3	10
			a	Exarane	JU	MP NP	P4910	20	3	10
			a	Clexane Safety-Lock	AV	MP NP		20	1	10
			a	Exarane	JU	MP NP		20	1	10
	Injection containing enoxaparin sodium 40 mg (4,000 I.U. anti-Xa) in 0.4 mL pre-filled syringe	Injection	a	Clexane Safety-Lock	AV	MP NP		20	3	10
			a	Exarane	JU	MP NP	P4910	20	3	10
			a	Clexane Safety-Lock	AV	MP NP		20	3	10
			a	Exarane	JU	MP NP	P4910	20	3	10
			a	Clexane Safety-Lock	AV	MP NP		10	1	10
			a	Exarane	JU	MP NP		10	1	10
Injection containing enoxaparin sodium 60 mg (6,000 I.U. anti-Xa) in 0.6 mL pre-filled syringe	Injection	a	Clexane Safety-Lock	AV	MP NP		10	1	10	
		a	Exarane	JU	MP NP		10	1	10	

		a	Clexane Safety-Lock	AV	MP NP	P4910	20	3	10
		a	Exarane	JU	MP NP	P4910	20	3	10
Injection containing enoxaparin sodium 80 mg (8,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe	Injection	a	Clexane Safety-Lock	AV	MP NP		10	1	10
		a	Exarane	JU	MP NP		10	1	10
Injection containing enoxaparin sodium 100 mg (10,000 I.U. anti-Xa) in 1 mL pre-filled syringe	Injection	a	Clexane Safety-Lock	AV	MP NP	P4910	20	3	10
		a	Exarane	JU	MP NP	P4910	20	3	10
		a	Clexane Safety-Lock	AV	MP NP		10	1	10
		a	Exarane	JU	MP NP		10	1	10
Injection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe	Injection	a	Clexane Safety-Lock	AV	MP NP	P4910	20	3	10
		a	Exarane	JU	MP NP	P4910	20	3	10
		a	Clexane Forte Safety-Lock	AV	MP NP		10	1	10
Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre-filled syringe	Injection	a	Exarane Forte	JU	MP NP		10	1	10
			Exarane Forte	JU	MP NP	P4910	10	3	10
Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre-filled syringe	Injection	a	Clexane Forte Safety-Lock	AV	MP NP		10	1	10
		a	Exarane Forte	JU	MP NP		10	1	10
			Exarane Forte	JU	MP NP	P4910	10	3	10

[123] Schedule 1, Part 1, after entry for Etanercept in the form Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL [Maximum Quantity: See Note 3; Number of Repeats: See Note 3]

insert:

MP	C7289 C8839	P14508 P14509	2	1	1
	C8842 C8873				
	C8879 C9064				
	C9081 C9123				
	C9140 C9162				
	C9377 C9380				
	C9386 C9388				
	C9410 C9429				
	C9473 C9487				
	C9502 C9554				
	C11107 C12164				
	C12261 C13532				
	C13533 C13535				
	C13538 C13540				
	C13593 C13598				
	C13646 C13647				
	C14382 C14427				
	C14483 C14486				
	C14488 C14493				
	C14498 C14499				
	C14507 C14508				
	C14509 C14513				
	C14552 C14553				
	C14554 C14576				
	C14577 C14600				

[124] Schedule 1, Part 1, entry for Etanercept in the form Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL [Maximum Quantity: 2; Number of Repeats: 3]

- (a) omit from the column headed "Circumstances": **C8638 C8662 C8692 C8718**
- (b) omit from the column headed "Circumstances": **C12260**
- (c) omit from the column headed "Circumstances": **C12262 C12265 C12266 C12287 C12289 C12327 C12434 C12457**
- (d) omit from the column headed "Circumstances": **C13542**
- (e) omit from the column headed "Circumstances": **C13707 C14108**
- (f) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600**

- (g) omit from the column headed "Purposes": **P8638**
- (h) omit from the column headed "Purposes": **P12260**
- (i) omit from the column headed "Purposes": **P12262 P12265 P12266 P12287 P12289 P12327 P12434 P12457**
- (j) omit from the column headed "Purposes": **P13542**
- (k) omit from the column headed "Purposes": **P13707 P14108**
- (l) insert in numerical order in the column headed "Purposes": **P14483 P14486 P14488 P14498 P14513 P14552 P14553 P14554 P14576 P14577 P14600**

**[125] Schedule 1, Part 1, entry for Etanercept in the form Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL [Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only: Nil]**

- (a) omit from the column headed "Circumstances": **C8638 C8662 C8692 C8718**
- (b) omit from the column headed "Circumstances": **C12260**
- (c) omit from the column headed "Circumstances": **C12262 C12265 C12266 C12287 C12289 C12327 C12434 C12457**
- (d) omit from the column headed "Circumstances": **C13542**
- (e) omit from the column headed "Circumstances": **C13707 C14108**
- (f) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600**
- (g) omit from the column headed "Purposes": **P8662 P8692 P8718**
- (h) insert in numerical order in the column headed "Purposes": **P14493 P14499 P14507**

**[126] Schedule 1, Part 1, after entry for Etanercept in the form Injection 50 mg in 1 mL single use auto-injector, 4 [Brand: Enbrel; Maximum Quantity: See Note 3; Number of Repeats: See Note 3]**

*insert:*

	MP	C7289 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9410 C9429 C9473 C9487	P14508 P14509	1	1	1
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C9502 C9554  
C11107 C12164  
C12261 C13532  
C13533 C13535  
C13538 C13540  
C13593 C13598  
C13646 C13647  
C14382 C14427  
C14483 C14486  
C14488 C14493  
C14498 C14499  
C14507 C14508  
C14509 C14513  
C14552 C14553  
C14554 C14576  
C14577 C14600

[127] Schedule 1, Part 1, entry for Etanercept in the form Injection 50 mg in 1 mL single use auto-injector, 4 [Brand: Brenzys; Maximum Quantity: 1; Number of Repeats: 3]

- (a) omit from the column headed "Circumstances": **C7276**
- (b) omit from the column headed "Circumstances": **C8638 C8662 C8692 C8718**
- (c) omit from the column headed "Circumstances": **C13542**
- (d) omit from the column headed "Circumstances": **C13707 C14108**
- (e) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14581 C14582 C14603 C14629**
- (f) omit from the column headed "Purposes": **P8638**
- (g) omit from the column headed "Purposes": **P13542**
- (h) omit from the column headed "Purposes": **P13707 P14108**
- (i) insert in numerical order in the column headed "Purposes": **P14483 P14486 P14488 P14498 P14581 P14582 P14603**

[128] Schedule 1, Part 1, entry for Etanercept in the form Injection 50 mg in 1 mL single use auto-injector, 4 [Brand: Enbrel; Maximum Quantity: 1; Number of Repeats: 3]

- (a) omit from the column headed "Circumstances": **C8638 C8662 C8692 C8718**
- (b) omit from the column headed "Circumstances": **C12260**

- 
- (c) omit from the column headed "Circumstances": **C12262 C12265 C12266 C12287 C12289 C12327 C12434 C12457**
  - (d) omit from the column headed "Circumstances": **C13542**
  - (e) omit from the column headed "Circumstances": **C13707 C14108**
  - (f) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600**
  - (g) omit from the column headed "Purposes": **P8638**
  - (h) omit from the column headed "Purposes": **P12260**
  - (i) omit from the column headed "Purposes": **P12262 P12265 P12266 P12287 P12289 P12327 P12434 P12457**
  - (j) omit from the column headed "Purposes": **P13542**
  - (k) omit from the column headed "Purposes": **P13707 P14108**
  - (l) insert in numerical order in the column headed "Purposes": **P14483 P14486 P14488 P14498 P14513 P14552 P14553 P14554 P14576 P14577 P14600**

**[129] Schedule 1, Part 1, entry for Etanercept in the form Injection 50 mg in 1 mL single use auto-injector, 4 [Brand: Brenzys; Maximum Quantity: 1; Number of Repeats: 5]**

- (a) omit from the column headed "Circumstances": **C7276**
- (b) omit from the column headed "Circumstances": **C8638 C8662 C8692 C8718**
- (c) omit from the column headed "Circumstances": **C13542**
- (d) omit from the column headed "Circumstances": **C13707 C14108**
- (e) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14581 C14582 C14603 C14629**
- (f) omit from the column headed "Purposes": **P7276**
- (g) omit from the column headed "Purposes": **P8662 P8692 P8718**
- (h) insert in numerical order in the column headed "Purposes": **P14493 P14499 P14507 P14629**

**[130] Schedule 1, Part 1, entry for Etanercept in the form Injection 50 mg in 1 mL single use auto-injector, 4 [Brand: Enbrel; Maximum Quantity: 1; Number of Repeats: 5; Section 100/ Prescriber Bag only: Nil]**

- (a) omit from the column headed "Circumstances": **C8638 C8662 C8692 C8718**
- (b) omit from the column headed "Circumstances": **C12260**

- (c) omit from the column headed "Circumstances": **C12262 C12265 C12266 C12287 C12289 C12327 C12434 C12457**
- (d) omit from the column headed "Circumstances": **C13542**
- (e) omit from the column headed "Circumstances": **C13707 C14108**
- (f) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600**
- (g) omit from the column headed "Purposes": **P8662 P8692 P8718**
- (h) insert in numerical order in the column headed "Purposes": **P14493 P14499 P14507**

**[131] Schedule 1, Part 1, after entry for Etanercept in the form Injections 50 mg in 1 mL single use pre-filled syringes, 4 [Brand: Enbrel; Maximum Quantity: See Note 3; Number of Repeats: See Note 3]**

*insert:*

	MP	C7289 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9410 C9429 C9473 C9487 C9502 C9554 C11107 C12164 C12261 C13532 C13533 C13535 C13538 C13540 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600	P14508 P14509	1	1	1
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[132] **Schedule 1, Part 1, entry for Etanercept in the form Injections 50 mg in 1 mL single use pre-filled syringes, 4 [Brand: Brenzys; Maximum Quantity: 1; Number of Repeats: 3]**

- (a) *omit from the column headed "Circumstances":* **C7276**
- (b) *omit from the column headed "Circumstances":* **C8638 C8662 C8692 C8718**
- (c) *omit from the column headed "Circumstances":* **C13542**
- (d) *omit from the column headed "Circumstances":* **C13707 C14108**
- (e) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14581 C14582 C14603 C14629**
- (f) *omit from the column headed "Purposes":* **P8638**
- (g) *omit from the column headed "Purposes":* **P13542**
- (h) *omit from the column headed "Purposes":* **P13707 P14108**
- (i) *insert in numerical order in the column headed "Purposes":* **P14483 P14486 P14488 P14498 P14581 P14582 P14603**

[133] **Schedule 1, Part 1, entry for Etanercept in the form Injections 50 mg in 1 mL single use pre-filled syringes, 4 [Brand: Enbrel; Maximum Quantity: 1; Number of Repeats: 3]**

- (a) *omit from the column headed "Circumstances":* **C8638 C8662 C8692 C8718**
- (b) *omit from the column headed "Circumstances":* **C12260**
- (c) *omit from the column headed "Circumstances":* **C12262 C12265 C12266 C12287 C12289 C12327 C12434 C12457**
- (d) *omit from the column headed "Circumstances":* **C13542**
- (e) *omit from the column headed "Circumstances":* **C13707 C14108**
- (f) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600**
- (g) *omit from the column headed "Purposes":* **P8638**
- (h) *omit from the column headed "Purposes":* **P12260**
- (i) *omit from the column headed "Purposes":* **P12262 P12265 P12266 P12287 P12289 P12327 P12434 P12457**
- (j) *omit from the column headed "Purposes":* **P13542**
- (k) *omit from the column headed "Purposes":* **P13707 P14108**

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(l) *insert in numerical order in the column headed "Purposes":* **P14483 P14486 P14488 P14498 P14513 P14552 P14553 P14554 P14576 P14577 P14600**

**[134] Schedule 1, Part 1, entry for Etanercept in the form Injections 50 mg in 1 mL single use pre-filled syringes, 4 [Brand: Brenzys; Maximum Quantity: 1; Number of Repeats: 5]**

(a) *omit from the column headed "Circumstances":* **C7276**

(b) *omit from the column headed "Circumstances":* **C8638 C8662 C8692 C8718**

(c) *omit from the column headed "Circumstances":* **C13542**

(d) *omit from the column headed "Circumstances":* **C13707 C14108**

(e) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14581 C14582 C14603 C14629**

(f) *omit from the column headed "Purposes":* **P7276**

(g) *omit from the column headed "Purposes":* **P8662 P8692 P8718**

(h) *insert in numerical order in the column headed "Purposes":* **P14493 P14499 P14507 P14629**

**[135] Schedule 1, Part 1, entry for Etanercept in the form Injections 50 mg in 1 mL single use pre-filled syringes, 4 [Brand: Enbrel; Maximum Quantity: 1; Number of Repeats: 5; Section 100/ Prescriber Bag only: Nil]**

(a) *omit from the column headed "Circumstances":* **C8638 C8662 C8692 C8718**

(b) *omit from the column headed "Circumstances":* **C12260**

(c) *omit from the column headed "Circumstances":* **C12262 C12265 C12266 C12287 C12289 C12327 C12434 C12457**

(d) *omit from the column headed "Circumstances":* **C13542**

(e) *omit from the column headed "Circumstances":* **C13707 C14108**

(f) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600**

(g) *omit from the column headed "Purposes":* **P8662 P8692 P8718**

(h) *insert in numerical order in the column headed "Purposes":* **P14493 P14499 P14507**

**[136] Schedule 1, Part 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-10 mg [Maximum Quantity: 30; Number of Repeats: 5]**  
*insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

a	Zimybe 10/10	MQ	MP	NP	C7958	C14269	P7958	30	5	30
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**[137] Schedule 1, Part 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-10 mg [Maximum Quantity: 60; Number of Repeats: 5]**  
*insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

a	Zimybe 10/10	MQ	MP	NP	C7958	C14269	P14269	60	5	30
---	--------------	----	----	----	-------	--------	--------	----	---	----

**[138] Schedule 1, Part 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-20 mg [Maximum Quantity: 30; Number of Repeats: 5]**  
*insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

a	Zimybe 10/20	MQ	MP	NP	C7958	C14269	P7958	30	5	30
---	--------------	----	----	----	-------	--------	-------	----	---	----

**[139] Schedule 1, Part 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-20 mg [Maximum Quantity: 60; Number of Repeats: 5]**  
*insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

a	Zimybe 10/20	MQ	MP	NP	C7958	C14269	P14269	60	5	30
---	--------------	----	----	----	-------	--------	--------	----	---	----

**[140] Schedule 1, Part 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-40 mg [Maximum Quantity: 30; Number of Repeats: 5]**  
*insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

a	Zimybe 10/40	MQ	MP	NP	C7957	C14284	P7957	30	5	30
---	--------------	----	----	----	-------	--------	-------	----	---	----

**[141] Schedule 1, Part 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-40 mg [Maximum Quantity: 60; Number of Repeats: 5]**  
*insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

a	Zimybe 10/40	MQ	MP	NP	C7957	C14284	P14284	60	5	30
---	--------------	----	----	----	-------	--------	--------	----	---	----

**[142] Schedule 1, Part 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-80 mg [Maximum Quantity: 30; Number of Repeats: 5]**  
*insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

a	Zimybe 10/80	MQ	MP	NP	C7957	C14284	P7957	30	5	30
---	--------------	----	----	----	-------	--------	-------	----	---	----

**[143] Schedule 1, Part 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-80 mg [Maximum Quantity: 60; Number of Repeats: 5]**  
*insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

a	Zimybe 10/80	MQ	MP	NP	C7957	C14284	P14284	60	5	30
---	--------------	----	----	----	-------	--------	--------	----	---	----

**[144] Schedule 1, Part 1, entry for Fenofibrate in the form Tablet 48 mg [Maximum Quantity: 120; Number of Repeats: 5]**

*omit from the column headed "Authorised Prescriber" (all instances):* **MP** *substitute (all instances):* **MP NP**

**[145] Schedule 1, Part 1, entry for Fenofibrate in the form Tablet 145 mg [Maximum Quantity: 60; Number of Repeats: 5]**

*omit from the column headed "Authorised Prescriber" (all instances):* **MP** *substitute (all instances):* **MP NP**

**[146] Schedule 1, Part 1, entry for Fluvastatin in the form Tablet (prolonged release) 80 mg (as sodium) [Maximum Quantity: 56; Number of Repeats: 5]**

*omit from the column headed "Authorised Prescriber":* **MP** *substitute:* **MP NP**

**[147] Schedule 1, Part 1, entry for Fosaprepitant**

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

	a	FOSAPREPITANT MSN	RQ	MP NP	C6852 C6886 C6887 C6891	1	5	1
--	---	----------------------	----	-------	----------------------------	---	---	---

**[148] Schedule 1, Part 1, entry for Fremanezumab**

*substitute:*

Fremanezumab	Solution for injection 225 mg in 1.5 mL single dose pre-filled pen	Injection	Ajovy	TB	MP	C14472 C14563 P14472	1	2	1
					MP	C14472 C14563 P14563	1	5	1
	Solution for injection 225 mg in 1.5 mL single dose pre-filled syringe	Injection	Ajovy	TB	MP	C14472 C14563 P14472	1	2	1
					MP	C14472 C14563 P14563	1	5	1

**[149] Schedule 1, Part 1, entry for Glimepiride in the form Tablet 4 mg**

*omit:*

	a	Amaryl	SW	MP NP		30	5	30
--	---	--------	----	-------	--	----	---	----

**[150] Schedule 1, Part 1, entry for Glycomacropeptide and essential amino acids with vitamins and minerals**

*omit:*

Sachets containing oral powder 49 g, 30 (Camino Pro Bettermilk)	Oral	Camino Pro Bettermilk	QH	MP	NP	C4295	4	5	1
--	------	--------------------------	----	----	----	-------	---	---	---

**[151] Schedule 1, Part 1, after entry for Glycomacropeptide and essential amino acids with vitamins and minerals in the form Sachets containing oral powder 32 g, 30 (PKU Build 20)**

*insert:*

Sachets containing oral powder 40 g, 30 (Camino Pro Bettermilk)	Oral	Camino Pro Bettermilk	QH	MP	NP	C4295	4	5	1
--	------	--------------------------	----	----	----	-------	---	---	---

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

- (a) *omit from the column headed "Circumstances":* **C8641 C8642 C8713**
- (b) *omit from the column headed "Circumstances":* **C11779 C11780 C14171**
- (c) *insert in numerical order in the column headed "Circumstances":* **C14488 C14507 C14519 C14556 C14557 C14604 C14626**
- (d) *omit from the column headed "Purposes":* **P8713**
- (e) *omit from the column headed "Purposes":* **P11779 P11780 P14171**
- (f) *insert in numerical order in the column headed "Purposes":* **P14488 P14556 P14557 P14626**

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

- (a) *omit from the column headed "Circumstances":* **C8641 C8642 C8713**
- (b) *omit from the column headed "Circumstances":* **C11779 C11780 C14171**
- (c) *insert in numerical order in the column headed "Circumstances":* **C14488 C14507 C14519 C14556 C14557 C14604 C14626**
- (d) *omit from the column headed "Purposes":* **P8641 P8642**
- (e) *insert in numerical order in the column headed "Purposes":* **P14507 P14519 P14604**

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

- (a) *omit from the column headed "Circumstances":* **C8641 C8642 C8713**
- (b) *omit from the column headed "Circumstances":* **C11779 C11780 C14171**
- (c) *insert in numerical order in the column headed "Circumstances":* **C14488 C14507 C14519 C14556 C14557 C14604 C14626**



- (d) omit from the column headed "Purposes": **P8713**
- (e) omit from the column headed "Purposes": **P11779 P11780 P14171**
- (f) insert in numerical order in the column headed "Purposes": **P14488 P14556 P14557 P14626**

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

- (a) omit from the column headed "Circumstances": **C8641 C8642 C8713**
- (b) omit from the column headed "Circumstances": **C11779 C11780 C14171**
- (c) insert in numerical order in the column headed "Circumstances": **C14488 C14507 C14519 C14556 C14557 C14604 C14626**
- (d) omit from the column headed "Purposes": **P8641 P8642**
- (e) insert in numerical order in the column headed "Purposes": **P14507 P14519 P14604**

**[156] Schedule 1, Part 1, entry for Ibuprofen in the form Tablet 400 mg [Maximum Quantity: 30; Number of Repeats: 0]**

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

a	MEDICHOICE Ibuprofen 400 mg	NB	MP NP MW PDP	30	0	30
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**[157] Schedule 1, Part 1, entry for Ibuprofen in the form Tablet 400 mg [Maximum Quantity: 90; Number of Repeats: 0]**

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

a	MEDICHOICE Ibuprofen 400 mg	NB	PDP	P6256 P6282	90	0	30
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**[158] Schedule 1, Part 1, entry for Ibuprofen in the form Tablet 400 mg [Maximum Quantity: 90; Number of Repeats: 3]**

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

a	MEDICHOICE Ibuprofen 400 mg	NB	MP NP	P6149 P6214 P6283	90	3	30
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**[159] Schedule 1, Part 1, after entry for Infliximab in the form Powder for I.V. infusion 100 mg [Brand: Renflexis; Maximum Quantity: See Note 3; Number of Repeats: See Note 3]**

*insert:*

Inflixtra	PF	MP	C14504 C14505	3	2	1	PB(100)
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				C14585 C14638				
	Remicade	JC	MP	C14504 C14505	3	2	1	PB(100)
	Renflexis	OQ	MP	C14504 C14505 C14585 C14638	3	2	1	PB(100)

- [160] **Schedule 1, Part 1, entry for Infliximab in the form Solution for injection 120 mg in 1 mL pre-filled pen [Maximum Quantity: 1; Number of Repeats: 0]**
- (a) *omit from the column headed "Circumstances": C11828*
- (b) *insert in numerical order in the column headed "Circumstances": C14515*
- [161] **Schedule 1, Part 1, entry for Infliximab in the form Solution for injection 120 mg in 1 mL pre-filled pen [Maximum Quantity: 2; Number of Repeats: 0]**
- (a) *omit from the column headed "Circumstances": C11828*
- (b) *insert in numerical order in the column headed "Circumstances": C14515*
- [162] **Schedule 1, Part 1, entry for Infliximab in the form Solution for injection 120 mg in 1 mL pre-filled pen [Maximum Quantity: 2; Number of Repeats: 2]**
- (a) *omit from the column headed "Circumstances": C11828*
- (b) *insert in numerical order in the column headed "Circumstances": C14515*
- [163] **Schedule 1, Part 1, entry for Infliximab in the form Solution for injection 120 mg in 1 mL pre-filled pen [Maximum Quantity: 2; Number of Repeats: 5]**
- (a) *omit from the column headed "Circumstances": C11828*
- (b) *insert in numerical order in the column headed "Circumstances": C14515*
- (c) *omit from the column headed "Purposes": P11828*
- (d) *insert in numerical order in the column headed "Purposes": P14515*
- [164] **Schedule 1, Part 1, entry for Infliximab in the form Solution for injection 120 mg in 1 mL pre-filled syringe [Maximum Quantity: 1; Number of Repeats: 0]**
- (a) *omit from the column headed "Circumstances": C11828*
- (b) *insert in numerical order in the column headed "Circumstances": C14515*

[165] **Schedule 1, Part 1, entry for Infliximab in the form Solution for injection 120 mg in 1 mL pre-filled syringe [Maximum Quantity: 2; Number of Repeats: 0]**

- (a) *omit from the column headed "Circumstances": C11828*
- (b) *insert in numerical order in the column headed "Circumstances": C14515*

[166] **Schedule 1, Part 1, entry for Infliximab in the form Solution for injection 120 mg in 1 mL pre-filled syringe [Maximum Quantity: 2; Number of Repeats: 2]**

- (a) *omit from the column headed "Circumstances": C11828*
- (b) *insert in numerical order in the column headed "Circumstances": C14515*

[167] **Schedule 1, Part 1, entry for Infliximab in the form Solution for injection 120 mg in 1 mL pre-filled syringe [Maximum Quantity: 2; Number of Repeats: 5]**

- (a) *omit from the column headed "Circumstances": C11828*
- (b) *insert in numerical order in the column headed "Circumstances": C14515*
- (c) *omit from the column headed "Purposes": P11828*
- (d) *insert in numerical order in the column headed "Purposes": P14515*

[168] **Schedule 1, Part 1, entry for Irinotecan in the form I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL**  
*insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

	IRINOTECAN BAXTER	BX	MP		See Note 3	See Note 3	1	D(100)
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[169] **Schedule 1, Part 1, entry for Levothyroxine in each of the forms: Tablet containing 50 micrograms anhydrous levothyroxine sodium; Tablet containing 75 micrograms anhydrous levothyroxine sodium; and Tablet containing 100 micrograms anhydrous levothyroxine sodium**

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

	a	Levothyroxine Sandoz	SZ	MP NP		200	1	200
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[170] **Schedule 1, Part 1, entry for Levothyroxine in the form Tablet containing 200 micrograms anhydrous levothyroxine sodium**  
*insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

			a	Levothyroxine Sandoz	SZ	MP NP			200	1	200
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**[171] Schedule 1, Part 1, entry for Lidocaine in the form Injection containing lidocaine hydrochloride monohydrate 50 mg in 5 mL**

**(a)** omit from the column headed "Brand": **Pfizer Australia Pty Ltd** substitute: **Lignocaine Injection (Pfizer)**

**(b)** omit from the column headed "Responsible Person": **PF** substitute: **WZ**

**[172] Schedule 1, Part 1, entry for Methylprednisolone**

substitute:

Methylprednisolone	Cream containing methylprednisolone aceponate 1 mg per g, 15 g	Application	a	Advantan	LO	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P4957	1	0	1
			a	Supriad Cream	LG	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P4957	1	0	1
			a	Advantan	LO	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6232	2	5	1
			a	Supriad Cream	LG	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6232	2	5	1
			a	Advantan	LO	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6246	4	5	1
			a	Supriad Cream	LG	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6246	4	5	1
			a	Advantan	LO	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6218	6	5	1
			a	Supriad Cream	LG	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6218	6	5	1

		a	Advantan	LO	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6263	8	5	1						
		a	Supriad Cream	LG	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6263	8	5	1						
		a	Advantan	LO	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6231	10	5	1						
		a	Supriad Cream	LG	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6231	10	5	1						
	Injection containing methylprednisolone acetate 40 mg in 1 mL	a	Depo-Medrol	PF	MP NP	C6273		5	0	5						
					PDP	C6209		5	0	5						
		a	Depo-Nisolone	FZ	MP NP	C6273		5	0	5						
					PDP	C6209		5	0	5						
	Lotion containing methylprednisolone aceponate 1 mg per g, 20 g	Application	Advantan	LO	MP NP	C6218 C6231 C6232 C6246 C6263 C6302	P6302	1	0	1						
											MP NP	C6218 C6231 C6232 C6246 C6263 C6302	P6232	2	5	1
											MP NP	C6218 C6231 C6232 C6246 C6263 C6302	P6246	3	5	1
											MP NP	C6218 C6231 C6232 C6246 C6263 C6302	P6218 P6263	4	5	1
				MP NP	C6218 C6231 C6232 C6246	P6231	5	5	1							

						C6263 C6302				
Fatty ointment containing methylprednisolone aceponate 1 mg per g, 15 g	Application	a	Advantan (Fatty)	LO	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P4957	1	0	1
		a	Supriad Fatty Ointment	LG	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P4957	1	0	1
		a	Tanilone (Fatty)	AS	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P4957	1	0	1
		a	Advantan (Fatty)	LO	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6232	2	5	1
		a	Supriad Fatty Ointment	LG	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6232	2	5	1
		a	Tanilone (Fatty)	AS	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6232	2	5	1
		a	Advantan (Fatty)	LO	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6246	4	5	1
		a	Supriad Fatty Ointment	LG	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6246	4	5	1
		a	Tanilone (Fatty)	AS	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6246	4	5	1
		a	Advantan (Fatty)	LO	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6218	6	5	1
	a	Supriad Fatty Ointment	LG	MP NP	C4957 C6218 C6231 C6232	P6218	6	5	1	

						C6246 C6263				
	a	Tanilone (Fatty)	AS	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6218	6	5	1	
	a	Advantan (Fatty)	LO	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6263	8	5	1	
	a	Supriad Fatty Ointment	LG	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6263	8	5	1	
	a	Tanilone (Fatty)	AS	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6263	8	5	1	
	a	Advantan (Fatty)	LO	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6231	10	5	1	
	a	Supriad Fatty Ointment	LG	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6231	10	5	1	
	a	Tanilone (Fatty)	AS	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6231	10	5	1	
Ointment containing methylprednisolone aceponate 1 mg per g, 15 g	Application	a	Advantan	LO	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P4957	1	0	1
	a	Supriad Ointment	LG	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P4957	1	0	1	
	a	Advantan	LO	MP NP	C4957 C6218 C6231 C6232 C6246 C6263	P6232	2	5	1	
	a	Supriad Ointment	LG	MP NP	C4957 C6218 C6231 C6232	P6232	2	5	1	

						C6246 C6263				
a	Advantan	LO	MP NP			C4957 C6218 C6231 C6232 C6246 C6263	P6246	4	5	1
a	Supriad Ointment	LG	MP NP			C4957 C6218 C6231 C6232 C6246 C6263	P6246	4	5	1
a	Advantan	LO	MP NP			C4957 C6218 C6231 C6232 C6246 C6263	P6218	6	5	1
a	Supriad Ointment	LG	MP NP			C4957 C6218 C6231 C6232 C6246 C6263	P6218	6	5	1
a	Advantan	LO	MP NP			C4957 C6218 C6231 C6232 C6246 C6263	P6263	8	5	1
a	Supriad Ointment	LG	MP NP			C4957 C6218 C6231 C6232 C6246 C6263	P6263	8	5	1
a	Advantan	LO	MP NP			C4957 C6218 C6231 C6232 C6246 C6263	P6231	10	5	1
a	Supriad Ointment	LG	MP NP			C4957 C6218 C6231 C6232 C6246 C6263	P6231	10	5	1
	Powder for injection 40 mg (as sodium succinate)	Injection		Methylpred	AL	MP NP		5	0	5
	Powder for injection 40 mg (as sodium succinate) with diluent	Injection		Solu-Medrol	PF	MP NP		5	0	1
	Powder for injection 40 mg (as sodium succinate) (S19A)	Injection		Solu-Medrone	LM	MP NP		5	0	1
	Powder for injection 1 g (as	Injection	a	Methylpred	AL	MP NP		1	0	1



sodium succinate)									
	a	Solu-Medrol	PF	MP NP		1	0	1	

**[173] Schedule 1, Part 1, entry for Naltrexone**

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

	a	ARX- NALTREXONE	XT	MP NP	C13967	30	1	30	
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(b) insert in the column headed "Schedule Equivalent" for the brand "Naltrexone GH": a

**[174] Schedule 1, Part 1, entry for Olanzapine in each of the forms: Powder for injection 210 mg (as pamoate monohydrate) with diluent; Powder for injection 300 mg (as pamoate monohydrate) with diluent; and Powder for injection 405 mg (as pamoate monohydrate) with diluent**

omit from the column headed "Responsible Person": LY substitute: PB

**[175] Schedule 1, Part 1, entry for Olanzapine in each of the forms: Tablet 2.5 mg; and Tablet 5 mg**

omit from the column headed "Responsible Person" for the brand "Zyprexa": LY substitute: PB

**[176] Schedule 1, Part 1, entry for Olanzapine in each of the forms: Tablet 7.5 mg; and Tablet 10 mg**

omit from the column headed "Responsible Person" for the brand "Zyprexa": LY substitute: PB

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

omit from the column headed "Responsible Person" for the brand "Zyprexa Zydis": LY substitute: PB

**[178] Schedule 1, Part 1, entry for Pancreatic extract in the form Capsule (containing enteric coated minimicrospheres) providing not less than 10,000 BP units of lipase activity [Maximum Quantity: 1000; Number of Repeats: 10]**

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

**[179] Schedule 1, Part 1, entry for Pancreatic extract in the form Capsule (containing enteric coated minimicrospheres) providing not less than 25,000 BP units of lipase activity [Maximum Quantity: 400; Number of Repeats: 10]**

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

**[180] Schedule 1, Part 1, entry for Pancreatic extract in the form Capsule (containing enteric coated minimicrospheres) providing not less than 35,000 BP units of lipase activity [Maximum Quantity: 400; Number of Repeats: 10]**

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

[181] Schedule 1, Part 1, entry for Pancreatic extract in the form Granules (enteric coated) providing not less than 5,000 BP units of lipase activity per 100 mg, 20 g [Maximum Quantity: 6; Number of Repeats: 10]

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

[182] Schedule 1, Part 1, entry for Paracetamol in the form Tablet 665 mg (modified release)

(a) omit:

a	CHEMISTS' OWN OSTEO RELIEF PARACETAMOL	RF	MP NP	C6225 C6280	P6225	192	3	96
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(b) omit:

a	CHEMISTS' OWN OSTEO RELIEF PARACETAMOL	RF	MP NP	C6225 C6280	P6280	192	5	96
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[183] Schedule 1, Part 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 10 mg [Maximum Quantity: 60; Number of Repeats: 5]

omit from the column headed "Authorised Prescriber" (all instances): MP substitute (all instances): MP NP

[184] Schedule 1, Part 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 20 mg [Maximum Quantity: 60; Number of Repeats: 5]

omit from the column headed "Authorised Prescriber" (all instances): MP substitute (all instances): MP NP

[185] Schedule 1, Part 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 40 mg [Maximum Quantity: 60; Number of Repeats: 5]

omit from the column headed "Authorised Prescriber" (all instances): MP substitute (all instances): MP NP

[186] Schedule 1, Part 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 80 mg [Maximum Quantity: 60; Number of Repeats: 5]

omit from the column headed "Authorised Prescriber" (all instances): MP substitute (all instances): MP NP

[187] Schedule 1, Part 1, entry for Pregabalin in the form Capsule 300 mg

omit:

a	Pregabalin GH	GQ	MP NP	C4172		56	5	56
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- [188] **Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 5 mg (as calcium) [Maximum Quantity: 60; Number of Repeats: 5]**  
*omit from the column headed "Authorised Prescriber" (all instances): MP substitute (all instances): MP NP*
- [189] **Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 10 mg (as calcium) [Maximum Quantity: 60; Number of Repeats: 5]**  
*omit from the column headed "Authorised Prescriber" (all instances): MP substitute (all instances): MP NP*
- [190] **Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 20 mg (as calcium) [Maximum Quantity: 60; Number of Repeats: 5]**  
*omit from the column headed "Authorised Prescriber" (all instances): MP substitute (all instances): MP NP*
- [191] **Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 40 mg (as calcium) [Maximum Quantity: 60; Number of Repeats: 5]**  
*omit from the column headed "Authorised Prescriber" (all instances): MP substitute (all instances): MP NP*
- [192] **Schedule 1, Part 1, entry for Simvastatin in the form Tablet 5 mg [Maximum Quantity: 60; Number of Repeats: 5]**  
*omit from the column headed "Authorised Prescriber" (all instances): MP substitute (all instances): MP NP*
- [193] **Schedule 1, Part 1, entry for Simvastatin in the form Tablet 10 mg [Maximum Quantity: 60; Number of Repeats: 5]**  
*omit from the column headed "Authorised Prescriber" (all instances): MP substitute (all instances): MP NP*
- [194] **Schedule 1, Part 1, entry for Simvastatin in the form Tablet 20 mg [Maximum Quantity: 60; Number of Repeats: 5]**  
*omit from the column headed "Authorised Prescriber" (all instances): MP substitute (all instances): MP NP*
- [195] **Schedule 1, Part 1, entry for Simvastatin in the form Tablet 40 mg [Maximum Quantity: 60; Number of Repeats: 5]**  
*omit from the column headed "Authorised Prescriber" (all instances): MP substitute (all instances): MP NP*
- [196] **Schedule 1, Part 1, entry for Simvastatin in the form Tablet 80 mg [Maximum Quantity: 60; Number of Repeats: 5]**  
*omit from the column headed "Authorised Prescriber" (all instances): MP substitute (all instances): MP NP*
- [197] **Schedule 1, Part 1, entry for Somatropin in the form Solution for injection 6 mg (18 i.u.) in 1.03 mL cartridge (with preservative)**  
(a) *insert in numerical order in the column headed "Circumstances": C12588*  
(b) *insert in numerical order in the column headed "Circumstances": C14366 C14390 C14431*
- [198] **Schedule 1, Part 1, entry for Somatropin in the form Solution for injection 12 mg (36 i.u.) in 1.5 mL cartridge (with preservative)**  
(a) *insert in numerical order in the column headed "Circumstances": C12588*  
(b) *insert in numerical order in the column headed "Circumstances": C14366 C14390 C14431*
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- [199] **Schedule 1, Part 1, entry for Sulfasalazine in the form Tablet 500 mg [Maximum Quantity: 400; Number of Repeats: 5]**  
*omit from the column headed "Authorised Prescriber": MP substitute: MP NP*
- [200] **Schedule 1, Part 1, entry for Sulfasalazine in the form Tablet 500 mg (enteric coated) [Maximum Quantity: 400; Number of Repeats: 5]**  
*omit from the column headed "Authorised Prescriber" (all instances): MP substitute (all instances): MP NP*
- [201] **Schedule 1, Part 1, entry for Tocilizumab in the form Concentrate for injection 80 mg in 4 mL [Maximum Quantity: 2; Number of Repeats: 5]**  
(a) *insert in numerical order in the column headed "Circumstances": C14485 C14621*  
(b) *insert in numerical order in the column headed "Purposes": P14485 P14621*
- [202] **Schedule 1, Part 1, entry for Tocilizumab in the form Concentrate for injection 80 mg in 4 mL [Maximum Quantity: 4; Number of Repeats: 5]**  
*insert in numerical order in the column headed "Circumstances": C14485 C14621*
- [203] **Schedule 1, Part 1, entry for Tocilizumab in the form Concentrate for injection 200 mg in 10 mL [Maximum Quantity: 1; Number of Repeats: 5]**  
(a) *insert in numerical order in the column headed "Circumstances": C14485 C14621*  
(b) *insert in numerical order in the column headed "Purposes": P14485 P14621*
- [204] **Schedule 1, Part 1, entry for Tocilizumab in the form Concentrate for injection 200 mg in 10 mL [Maximum Quantity: 2; Number of Repeats: 5]**  
*insert in numerical order in the column headed "Circumstances": C14485 C14621*
- [205] **Schedule 1, Part 1, entry for Tocilizumab in the form Concentrate for injection 400 mg in 20 mL [Maximum Quantity: 1; Number of Repeats: 5]**  
(a) *insert in numerical order in the column headed "Circumstances": C14485 C14621*  
(b) *insert in numerical order in the column headed "Purposes": P14485 P14621*
- [206] **Schedule 1, Part 1, entry for Tocilizumab in the form Concentrate for injection 400 mg in 20 mL [Maximum Quantity: 2; Number of Repeats: 5]**  
*insert in numerical order in the column headed "Circumstances": C14485 C14621*
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- [207] **Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled pen [Maximum Quantity: 4; Number of Repeats: 0]**
- (a) *omit from the column headed "Circumstances":* **C8627 C8633 C8638**
  - (b) *omit from the column headed "Circumstances":* **C11689 C11781**
  - (c) *omit from the column headed "Circumstances":* **C14056**
  - (d) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14498 C14499 C14507**
- [208] **Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled pen [Maximum Quantity: 4; Number of Repeats: 1]**
- (a) *omit from the column headed "Circumstances":* **C8627 C8633 C8638**
  - (b) *omit from the column headed "Circumstances":* **C11689 C11781**
  - (c) *omit from the column headed "Circumstances":* **C14056**
  - (d) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14498 C14499 C14507**
- [209] **Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled pen [Maximum Quantity: 4; Number of Repeats: 2]**
- (a) *omit from the column headed "Circumstances":* **C8627 C8633 C8638**
  - (b) *omit from the column headed "Circumstances":* **C11689 C11781**
  - (c) *omit from the column headed "Circumstances":* **C14056**
  - (d) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14498 C14499 C14507**
- [210] **Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled pen [Maximum Quantity: 4; Number of Repeats: 3]**
- (a) *omit from the column headed "Circumstances":* **C8627 C8633 C8638**
  - (b) *omit from the column headed "Circumstances":* **C11689 C11781**
  - (c) *omit from the column headed "Circumstances":* **C14056**
  - (d) *insert in numerical order in the column headed "Circumstances":* **C14483 C14486 C14488 C14493 C14498 C14499 C14507**
  - (e) *omit from the column headed "Purposes":* **P8638**
  - (f) *omit from the column headed "Purposes":* **P11689 P11781**
  - (g) *omit from the column headed "Purposes":* **P14056**
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- (h) *insert in numerical order in the column headed "Purposes": P14483 P14486 P14488 P14498*
- [211] **Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled pen [Maximum Quantity: 4; Number of Repeats: 5]**
- (a) *omit from the column headed "Circumstances": C8627 C8633 C8638*
- (b) *omit from the column headed "Circumstances": C11689 C11781*
- (c) *omit from the column headed "Circumstances": C14056*
- (d) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14498 C14499 C14507*
- (e) *omit from the column headed "Purposes": P8627 P8633*
- (f) *insert in numerical order in the column headed "Purposes": P14493 P14499 P14507*
- [212] **Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled pen [Maximum Quantity: 4; Number of Repeats: 6]**
- (a) *omit from the column headed "Circumstances": C8627 C8633 C8638*
- (b) *omit from the column headed "Circumstances": C11689 C11781*
- (c) *omit from the column headed "Circumstances": C14056*
- (d) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14498 C14499 C14507*
- [213] **Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled syringe [Maximum Quantity: 4; Number of Repeats: 0]**
- (a) *omit from the column headed "Circumstances": C8627 C8633 C8638*
- (b) *omit from the column headed "Circumstances": C11689 C11781*
- (c) *omit from the column headed "Circumstances": C14056*
- (d) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14498 C14499 C14507*
- [214] **Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled syringe [Maximum Quantity: 4; Number of Repeats: 1]**
- (a) *omit from the column headed "Circumstances": C8627 C8633 C8638*
- (b) *omit from the column headed "Circumstances": C11689 C11781*
- (c) *omit from the column headed "Circumstances": C14056*
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- (d) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14498 C14499 C14507*
- [215] Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled syringe [Maximum Quantity: 4; Number of Repeats: 2]**
- (a) *omit from the column headed "Circumstances": C8627 C8633 C8638*
- (b) *omit from the column headed "Circumstances": C11689 C11781*
- (c) *omit from the column headed "Circumstances": C14056*
- (d) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14498 C14499 C14507*
- [216] Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled syringe [Maximum Quantity: 4; Number of Repeats: 3]**
- (a) *omit from the column headed "Circumstances": C8627 C8633 C8638*
- (b) *omit from the column headed "Circumstances": C11689 C11781*
- (c) *omit from the column headed "Circumstances": C14056*
- (d) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14498 C14499 C14507*
- (e) *omit from the column headed "Purposes": P8638*
- (f) *omit from the column headed "Purposes": P11689 P11781*
- (g) *omit from the column headed "Purposes": P14056*
- (h) *insert in numerical order in the column headed "Purposes": P14483 P14486 P14488 P14498*
- [217] Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled syringe [Maximum Quantity: 4; Number of Repeats: 5]**
- (a) *omit from the column headed "Circumstances": C8627 C8633 C8638*
- (b) *omit from the column headed "Circumstances": C11689 C11781*
- (c) *omit from the column headed "Circumstances": C14056*
- (d) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14493 C14498 C14499 C14507*
- (e) *omit from the column headed "Purposes": P8627 P8633*
- (f) *insert in numerical order in the column headed "Purposes": P14493 P14499 P14507*
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- [218] Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled syringe [Maximum Quantity: 4; Number of Repeats: 6]**
- (a) omit from the column headed "Circumstances": **C8627 C8633 C8638**
  - (b) omit from the column headed "Circumstances": **C11689 C11781**
  - (c) omit from the column headed "Circumstances": **C14056**
  - (d) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14498 C14499 C14507**
- [219] 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": **C8627 C8638 C8725**
  - (b) omit from the column headed "Circumstances": **C11689 C11807**
  - (c) omit from the column headed "Circumstances": **C14185**
  - (d) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14498 C14499 C14507**
  - (e) omit from the column headed "Purposes": **P8638**
  - (f) omit from the column headed "Purposes": **P11689 P11807**
  - (g) omit from the column headed "Purposes": **P14185**
  - (h) insert in numerical order in the column headed "Purposes": **P14483 P14486 P14488 P14498**
- [220] 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": **C8627 C8638 C8725**
  - (b) omit from the column headed "Circumstances": **C11689 C11807**
  - (c) omit from the column headed "Circumstances": **C14185**
  - (d) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14493 C14498 C14499 C14507**
  - (e) omit from the column headed "Purposes": **P8627 P8725**
  - (f) insert in numerical order in the column headed "Purposes": **P14493 P14499 P14507**
- [221] Schedule 1, Part 1, after entry for Trastuzumab in the form Solution for subcutaneous injection containing trastuzumab 600 mg in 5 mL**  
insert:

Trastuzumab deruxtecan	Powder for I.V. infusion 100 mg	Injection	Enhertu	AP	MP	C14470	See Note 3	See Note 3	1	D(100)
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- [222] 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": C8638*
  - (b) *omit from the column headed "Circumstances": C10340 C10356*
  - (c) *omit from the column headed "Circumstances": C11488 C11813*
  - (d) *omit from the column headed "Circumstances": C14170*
  - (e) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14498 C14613 C14633*
- [223] 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": C8638*
  - (b) *omit from the column headed "Circumstances": C10340 C10356*
  - (c) *omit from the column headed "Circumstances": C11488 C11813*
  - (d) *omit from the column headed "Circumstances": C14170*
  - (e) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14498 C14613 C14633*
  - (f) *omit from the column headed "Purposes": P8638*
  - (g) *omit from the column headed "Purposes": P10340 P11813*
  - (h) *omit from the column headed "Purposes": P14170*
  - (i) *insert in numerical order in the column headed "Purposes": P14483 P14486 P14488 P14498*
- [224] 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": C8638*
  - (b) *omit from the column headed "Circumstances": C10340 C10356*
  - (c) *omit from the column headed "Circumstances": C11488 C11813*
  - (d) *omit from the column headed "Circumstances": C14170*
  - (e) *insert in numerical order in the column headed "Circumstances": C14483 C14486 C14488 C14498 C14613 C14633*
- [225] 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": C8638*
  - (b) *omit from the column headed "Circumstances": C10340 C10356*

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- (c) omit from the column headed "Circumstances": **C11488 C11813**
- (d) omit from the column headed "Circumstances": **C14170**
- (e) insert in numerical order in the column headed "Circumstances": **C14483 C14486 C14488 C14498 C14613 C14633**
- (f) omit from the column headed "Purposes": **P10356**
- (g) omit from the column headed "Purposes": **P11488**
- (h) insert in numerical order in the column headed "Purposes": **P14613 P14633**
- [226] Schedule 1, Part 1, entry for Ursodeoxycholic acid in each of the forms: Capsule 250 mg; and Tablet 500 mg**  
omit from the column headed "Number of Repeats" (all instances): **2** substitute (all instances): **4**
- [227] Schedule 1, Part 1, entry for Ustekinumab in the form Injection 45 mg in 0.5 mL [Maximum Quantity: 1; Number of Repeats: 0]**
- (a) omit from the column headed "Circumstances": **C12294 C12302 C12311 C12323 C12332 C12333**
- (b) omit from the column headed "Circumstances": **C12341**
- (c) insert in numerical order in the column headed "Circumstances": **C14543 C14558 C14572 C14573 C14628 C14636 C14643**
- [228] Schedule 1, Part 1, entry for Ustekinumab in the form Injection 45 mg in 0.5 mL [Maximum Quantity: 1; Number of Repeats: 1]**
- (a) omit from the column headed "Circumstances": **C12294 C12302 C12311 C12323 C12332 C12333**
- (b) omit from the column headed "Circumstances": **C12341**
- (c) insert in numerical order in the column headed "Circumstances": **C14543 C14558 C14572 C14573 C14628 C14636 C14643**
- (d) omit from the column headed "Purposes": **P12302 P12311**
- (e) insert in numerical order in the column headed "Purposes": **P14558 P14628**
- [229] Schedule 1, Part 1, entry for Ustekinumab in the form Injection 45 mg in 0.5 mL [Maximum Quantity: 1; Number of Repeats: 2]**
- (a) omit from the column headed "Circumstances": **C12294 C12302 C12311 C12323 C12332 C12333**
- (b) omit from the column headed "Circumstances": **C12341**
- (c) insert in numerical order in the column headed "Circumstances": **C14543 C14558 C14572 C14573 C14628 C14636 C14643**
- (d) omit from the column headed "Purposes": **P12294 P12323 P12332 P12333**
- (e) omit from the column headed "Purposes": **P12341**
- (f) insert in numerical order in the column headed "Purposes": **P14543 P14572 P14573 P14636 P14643**
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**[230] Schedule 1, Part 1, entry for Ustekinumab in the form Injection 45 mg in 0.5 mL [Maximum Quantity: 2; Number of Repeats: 0]**

**(a) omit from the column headed "Circumstances": C12294 C12302 C12311 C12323 C12332 C12333**

**(b) omit from the column headed "Circumstances": C12341**

**(c) insert in numerical order in the column headed "Circumstances": C14543 C14558 C14572 C14573 C14628 C14636 C14643**

**[231] Schedule 1, Part 1, entry for Valganciclovir in the form Tablet 450 mg (as hydrochloride)**

*omit:*

a	Valganciclovir Mylan	AF	MP	C4980 C4989 C9316	120	5	60	D(100)
			NP	C4980	120	5	60	D(100)

**[232] Schedule 1, Part 1, entry for Varenicline in the form Tablet 1 mg (as tartrate) [Maximum Quantity: 56; Number of Repeats: 2]**

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

	PHARMACOR VARENICLINE	CR	MP NP	C6885 C7483 P6885	56	2	56	
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**[233] Schedule 1, Part 1, entry for Varenicline in the form Tablet 1 mg (as tartrate) [Maximum Quantity: 112; Number of Repeats: 0]**

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

	PHARMACOR VARENICLINE	CR	MP NP	C6885 C7483 P7483	112	0	56	
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**[234] Schedule 1, Part 1, entry for Varenicline in the form Box containing 11 tablets 0.5 mg (as tartrate) and 14 tablets 1 mg (as tartrate) in the first pack and 28 tablets 1 mg (as tartrate) in the second pack**

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

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

a	PHARMACOR VARENICLINE	CR	MP NP	C6871	1	0	1	
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**[235] Schedule 1, Part 2, Ready-prepared pharmaceutical benefits for supply only**

*substitute:*

## Part 2—Ready-prepared pharmaceutical benefits for supply only

Note: Section 9 (authorised prescribers) does not apply to pharmaceutical benefits listed in this Part.

Listed Drug	Form	Manner of Administration	Schedule Equivalent	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Pack Quantity	Determined Quantity	Section 100/Prescriber Bag only
Amino acid formula with vitamins and minerals without phenylalanine	Sachets containing oral powder 24 g, 30 (PKU gel)	Oral		PKU gel	VF	MP NP	C4295		4	5	1		
Efavirenz	Tablet 200 mg	Oral		Stocrin	MK	MP NP	C4454 C4512		180	5	90		D(100)
	Tablet 600 mg	Oral		Stocrin	MK	MP NP	C4454 C4512		60	5	30		D(100)
Eprosartan	Tablet 400 mg (as mesilate)	Oral		Teveten	GO	MP NP			56	5	28		
						MP NP		P6328 P6329 P6332 P6351	56 CN6328 CN6329 CN6332 CN6351	5 CN6328 CN6329 CN6332 CN6351	28		
Ertugliflozin	Tablet 5 mg	Oral		Steglatro 5	MK	MP	C7495 C7506 C7528		28	5	28		
						NP	C7495 C7506		28	5	28		
	Tablet 15 mg	Oral		Steglatro 15	MK	MP	C7495 C7506 C7528		28	5	28		
						NP	C7495 C7506		28	5	28		
Ertugliflozin with sitagliptin	Tablet containing 5 mg ertugliflozin with 100 mg	Oral		Steglujan 5/100	MK	MP	C7524 C7556		28	5	28		

	sitagliptin				NP	C7556	28	5	28	
	Tablet containing 15 mg ertugliflozin with 100 mg sitagliptin	Oral		Steglujan 15/100	MK	MP C7524 C7556	28	5	28	
						NP	C7556	28	5	28
Labetalol	Tablet containing labetalol hydrochloride 200 mg	Oral	a	Trandate	AS	MP NP	100	5	100	

**[236] Schedule 3, after details relevant to Responsible Person code KY**

*insert:*

LG	Leo Pharma Pty Ltd	72 147 880 617
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**[237] Schedule 3, after details relevant to Responsible Person code MW**

*insert:*

NB	Nova Pharmaceuticals Australasia Pty Ltd	87 104 838 440
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**[238] Schedule 3, after details relevant to Responsible Person code WA**

*insert:*

WZ	Bridgewest Perth Pharma Pty Ltd	21 663 385 411
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**[239] Schedule 3**

*omit:*

ZA	AstraZeneca Pty Ltd	54 009 682 311
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**[240] Schedule 4, Part 1, entry for Abatacept**

*substitute:*

Abatacept	C14488	P14488		Severe active rheumatoid arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR	Compliance with Authority Required procedures
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			<p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR  Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND  The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p>	
	C14507	P14507	<p>Severe active rheumatoid arthritis  First 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 first continuing treatment restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment.</p>	Compliance with Authority Required procedures
	C14519	P14519	<p>Severe active rheumatoid arthritis  First continuing treatment  Must be treated by a rheumatologist; OR  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment 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 at least 18 years of age.  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).  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; and</p>	Compliance with Written Authority Required procedures

			<p>(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).</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>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.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>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.</p>	
	C14522	P14522	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>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 at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>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/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>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 contraindicated according to the relevant TGA-approved Product Information/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</p> <p>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</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.</p> <p>Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p>	Compliance with Written Authority Required procedures

			<p>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, however the time on treatment must be at least 6 months.</p> <p>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 including severity and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>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 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>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.</p> <p>At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>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.</p> <p>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.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>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.</p> <p>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.</p>	
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	C14555		<p>Severe active rheumatoid arthritis  Subsequent continuing treatment  Must be treated by a rheumatologist; OR  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR  Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment under this restriction; AND  The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.  Patient must be at least 18 years of age.  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).  The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.  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.  If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.  If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14555</p>
	C14560	P14560	<p>Severe active rheumatoid 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 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/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5</p>	<p>Compliance with Written Authority Required procedures</p>

			<p>times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.</p> <p>Patient must be at least 18 years of age.</p> <p>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).</p> <p>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>	
	C14583	P14583	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p>	Compliance with Written Authority Required procedures

			<p>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/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 at least 18 years of age.  Patients who have received PBS-subsidised 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.  Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.  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 is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a 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; 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).</p>	
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			<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>	
	C14604	P14604	<p>Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. 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). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. 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. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14604

				If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.	
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**[241] Schedule 4, Part 1, entry for Adalimumab**

(a) *omit:*

	C8638	P8638		<p>Severe active rheumatoid arthritis</p> <p>Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>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</p> <p>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</p> <p>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</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p>	Compliance with Authority Required procedures
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(b) *omit:*

	C11605	P11605		<p>Severe active rheumatoid arthritis</p> <p>Subsequent continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p>	Compliance with Authority Required procedures - Streamlined Authority Code 11605
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			<p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.</p> <p>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.</p>	
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(c) omit:

	C11720	P11720	<p>Severe active rheumatoid arthritis</p> <p>First continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>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).</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>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).</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>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</p>	Compliance with Written Authority Required procedures
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				<p>the necessity for permanent withdrawal of treatment.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>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.</p>	
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**(d) omit:**

	C11769	P11769		<p>Severe active rheumatoid arthritis</p> <p>Continuing Treatment - balance of supply</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.</p>	Compliance with Authority Required procedures
	C11772	P11772		<p>Severe active rheumatoid arthritis</p> <p>Subsequent continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p>	Compliance with Written Authority Required procedures

			<p>(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).</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>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.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>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.</p>	
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(e) omit:

	C13550	P13550	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>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</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>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).</p> <p>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p>	Compliance with Written Authority Required procedures
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			<p>(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).</p> <p>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.</p> <p>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.</p> <p>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.</p>	
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(f) omit:

	C13648	P13648	<p>Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p>	Compliance with Written Authority Required procedures
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			<p>The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>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.</p> <p>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 including severity and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:</p> <p>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</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>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 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>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.</p> <p>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.</p>	
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**(g)** omit:

	C14058	P14058	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p>	Compliance with Written Authority Required procedures
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			<p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR</p> <p>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</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>Patients who have received PBS-subsidised 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.</p> <p>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:</p> <p>(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</p> <p>(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).</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(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).</p> <p>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.</p> <p>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.</p>	
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(h) insert in numerical order after existing text:

	C14483	P14483	<p>Severe active rheumatoid 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 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/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 at least 18 years of age. Patients who have received PBS-subsidised 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. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. 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 is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a 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</p>	Compliance with Written Authority Required procedures
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			<p>with the initial application, the same marker must be used to determine response.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>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.</p> <p>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.</p>	
	C14486	P14486	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>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).</p> <p>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>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</p>	Compliance with Written Authority Required procedures

			<p>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.</p> <p>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.</p> <p>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.</p>	
	C14488	P14488	<p>Severe active rheumatoid arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p>	Compliance with Authority Required procedures
	C14493	P14493	<p>Severe active rheumatoid arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. 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). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be</p>	Compliance with Written Authority Required procedures

			<p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>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.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>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.</p>	
	C14496	P14496	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>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 at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>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/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>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 contraindicated according to the relevant TGA-approved Product Information/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</p> <p>Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of</p>	Compliance with Authority Required procedures

			<p>application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.</p> <p>The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>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, however the time on treatment must be at least 6 months.</p> <p>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 including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.</p> <p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>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 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>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.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:</p> <p>(a) the active joint count, ESR and/or CRP result and date of results;</p> <p>(b) details of prior treatment, including dose and date/duration of treatment.</p> <p>(c) If applicable, details of any contraindications/intolerances.</p> <p>(d) If applicable, the maximum tolerated dose of methotrexate.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>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.</p> <p>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.</p>	
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	C14498	P14498	<p>Severe active rheumatoid arthritis  Initial treatment - Initial 1 (new patient)  Must be treated by a rheumatologist; OR  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.  Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (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/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (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 contraindicated according to the relevant TGA-approved Product Information/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 at least 18 years of age.  If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.  The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.  The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.  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 including severity and dose for each DMARD must be provided in the authority application.  The following criteria indicate failure to achieve an adequate response to DMARD treatment 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 and/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</p>	Compliance with Written Authority Required procedures
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			<p>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 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>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.</p> <p>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.</p>	
	C14499	P14499	<p>Severe active rheumatoid arthritis</p> <p>Subsequent continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR</p> <p>Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14499</p>

			<p>weeks old at the time of the authority application.</p> <p>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.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>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.</p>	
	C14507	P14507	<p>Severe active rheumatoid arthritis</p> <p>First continuing treatment - balance of supply</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment.</p>	Compliance with Authority Required procedures
	C14567	P14567	<p>Severe active rheumatoid arthritis</p> <p>First continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>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.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14567

			not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14568	P14568	<p>Severe active rheumatoid 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 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/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. 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 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response 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 following information must be provided by the prescriber at the time of application and documented in the patient's medical records: (a) the active joint count, ESR and/or CRP result and date of result; (b) the most recent biological agent and the date of the last continuing prescription. (c) If applicable, the new baseline scores. 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</p>	Compliance with Authority Required procedures

			<p>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.</p>	
	C14590	P14590	<p>Severe active rheumatoid 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 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/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 at least 18 years of age. Patients who have received PBS-subsidised 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. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. 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). The assessment of response to treatment must be documented in the patient's medical records. An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a 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.</p>	Compliance with Authority Required procedures

			<p>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.</p> <p>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.</p> <p>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.</p>	
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**[242] Schedule 4, Part 1, entry for Baricitinib**

*substitute:*

Baricitinib	C14483	P14483	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR</p> <p>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</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Patients who have received PBS-subsidised 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.</p> <p>Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a</p>	Compliance with Written Authority Required procedures
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			<p>response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>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.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>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.</p> <p>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.</p>	
	C14486	P14486	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>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).</p> <p>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this</p>	Compliance with Written Authority Required procedures

			<p>criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response 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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>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.</p> <p>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.</p> <p>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.</p>	
	C14488	P14488	<p>Severe active rheumatoid arthritis</p> <p>Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>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</p> <p>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</p> <p>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</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p>	Compliance with Authority Required procedures
	C14493	P14493	<p>Severe active rheumatoid arthritis</p> <p>First continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p>	Compliance with Written Authority Required procedures



			<p>Patient must be at least 18 years of age.</p> <p>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).  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; 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).</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within 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 has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
	C14498	P14498	<p>Severe active rheumatoid arthritis  Initial treatment - Initial 1 (new patient)  Must be treated by a rheumatologist; OR  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.  Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (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/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of</p>	Compliance with Written Authority Required procedures

			<p>at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (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 contraindicated according to the relevant TGA-approved Product Information/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 at least 18 years of age.  If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.  The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.  The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.  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 including severity and dose for each DMARD must be provided in the authority application.  The following criteria indicate failure to achieve an adequate response to DMARD treatment 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 and/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 4 weeks old at the time of initial application.  If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response 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; 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).</p>	
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			<p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>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.</p> <p>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.</p>	
	C14499	P14499	<p>Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. 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). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. 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. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14499</p>
	C14507	P14507	<p>Severe active rheumatoid arthritis First 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.</p>	<p>Compliance with Authority Required procedures</p>

				<p>Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment.</p>	
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**[243] Schedule 4, Part 1, entry for Blinatumomab**

(a) *omit:*

	C9911			<p>Acute lymphoblastic leukaemia</p> <p>Induction treatment</p> <p>The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less; AND</p> <p>The condition must not be present in the central nervous system or testis; AND</p> <p>Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive; AND</p> <p>Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy; AND</p> <p>Patient must not have received more than 1 line of salvage therapy; AND</p> <p>Patient must not have received blinatumomab previously for the treatment of minimal residual disease; OR</p> <p>Patient must have had a relapse-free period of at least six months following completion of treatment with blinatumomab for minimal residual disease; AND</p> <p>The condition must have more than 5% blasts in bone marrow; AND</p> <p>The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.</p> <p>According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 9 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for 4 or more hours), supervision by a health care professional or hospitalisation is recommended.</p> <p>An amount of 651 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 1. An amount of 784 microgram, which may be obtained under Induction treatment - balance of supply restriction, will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 2.</p> <p>Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p> <p>The authority application must be made in writing and must include:</p> <ol style="list-style-type: none"> <li>(1) a completed authority prescription form; and</li> <li>(2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and</li> <li>(3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and</li> <li>(4) if applicable, the date of completion of blinatumomab treatment for minimal residual disease and the date of the patient's subsequent relapse; and</li> <li>(5) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application.</li> </ol>	Compliance with Written Authority Required procedures
	C9936			<p>Minimal residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)</p> <p>Continuing treatment of previously detectable minimal residual disease of Pre-B-cell ALL</p> <p>Must be treated by a physician experienced in the treatment of haematological malignancies.</p> <p>Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND</p> <p>Patient must have achieved a complete remission; AND</p>	Compliance with Authority Required procedures

			<p>Patient must be minimal residual disease negative, defined as either undetectable using the same method used to determine original eligibility or less than <math>10^{-4}</math>(0.01%) blasts based on measurement in bone marrow; AND</p> <p>Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.</p> <p>For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended.</p> <p>An amount of 784 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle.</p> <p>Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p> <p>Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.</p>	
	C9937		<p>Minimal residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)</p> <p>Initial treatment of minimal residual disease of Pre-B-cell ALL</p> <p>Must be treated by a physician experienced in the treatment of haematological malignancies.</p> <p>Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND</p> <p>The condition must not be present in the central nervous system or testis; AND</p> <p>Patient must have achieved complete remission following intensive combination chemotherapy for initial treatment of acute lymphoblastic leukaemia (ALL) or for subsequent salvage therapy; AND</p> <p>Patient must have minimal residual disease defined as at least <math>10^{-4}</math>(0.01%) blasts based on measurement in bone marrow, documented after an interval of at least 2 weeks from the last course of systemic chemotherapy given as intensive combination chemotherapy treatment of ALL or as subsequent salvage therapy, whichever was the later, and measured using polymerase chain reaction or flow cytometry; AND</p> <p>The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.</p> <p>According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 days of the first cycle and the first 2 days of the second cycle.</p> <p>For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended.</p> <p>An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle.</p> <p>Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Minimal residual disease positive Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and</p> <p>(3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy; and</p> <p>(4) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application</p> <p>Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.</p>	Compliance with Written Authority Required procedures

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

	C14587		<p>Measurable residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)</p> <p>Continuing treatment of previously measurable residual disease of Pre-B-cell ALL</p> <p>Must be treated by a physician experienced in the treatment of haematological malignancies.</p> <p>Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND</p>	Compliance with Authority Required procedures
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			<p>Patient must have achieved a complete remission; AND  The condition must be negative for measurable residual disease using the same method used to determine initial PBS eligibility; AND  Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND  The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.  For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended.  An amount of 784 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle.  Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.  Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.</p>	
	C14588		<p>Acute lymphoblastic leukaemia  Induction treatment  The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less; AND  The condition must not be present in the central nervous system or testis; AND  Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive; AND  Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy; AND  Patient must not have received more than 1 line of salvage therapy; AND  The condition must be one of the following: (i) untreated with this drug for measurable residual disease, (ii) treated with this drug for measurable residual disease, but the condition has not relapsed within 6 months of completing that course of treatment; AND  The condition must have more than 5% blasts in bone marrow; AND  The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.  According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 9 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for 4 or more hours), supervision by a health care professional or hospitalisation is recommended.  An amount of 651 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 1. An amount of 784 microgram, which may be obtained under Induction treatment - balance of supply restriction, will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 2.  Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.  The authority application must be made in writing and must include:  (1) a completed authority prescription form; and  (2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and  (3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and  (4) if applicable, the date of completion of blinatumomab treatment for measurable residual disease and the date of the patient's subsequent relapse; and  (5) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application.</p>	Compliance with Written Authority Required procedures
	C14631		<p>Measurable residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)</p>	Compliance with Written

			<p>Initial treatment of measurable residual disease of Pre-B-cell ALL          Must be treated by a physician experienced in the treatment of haematological malignancies.          Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND          The condition must not be present in the central nervous system or testis; AND          Patient must have achieved complete remission following intensive combination chemotherapy for initial treatment of acute lymphoblastic leukaemia (ALL) or for subsequent salvage therapy; AND          Patient must have measurable residual disease based on measurement in bone marrow, documented after an interval of at least 2 weeks from the last course of systemic chemotherapy given as intensive combination chemotherapy treatment of ALL/as subsequent salvage therapy, whichever was the later, measured using flow cytometry/molecular methods; AND          The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.          According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 days of the first cycle and the first 2 days of the second cycle.          For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended.          An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle.          Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.          The authority application must be made in writing and must include:          (1) a completed authority prescription form; and          (2) a completed Measurable residual disease positive Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and          (3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy; and          (4) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application.          Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.</p>	Authority Required procedures
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**[244] Schedule 4, Part 1, entry for Budesonide**

(a) *omit:*

	C12836	P12836	<p>Eosinophilic oesophagitis          First continuing treatment - Confirmation of remission          Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND          Patient must have documented evidence of having achieved histologic remission while receiving initial PBS-subsidised treatment with this drug for this condition, defined as a peak eosinophil count of less than 5 eosinophils per high power field (hpf), corresponding to less than 16 eosinophils per mm<sup>2</sup>hpf on oesophageal biopsy; AND          Patient must not receive more than 26 weeks of treatment under this restriction.          Must be treated by a gastroenterologist.          Histologic assessment should be based on the peak eosinophils count derived from the evaluation of at least eight oesophageal biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction).          The histologic assessment should, where possible, be performed by the same physician who confirmed the diagnosis of eosinophilic oesophagitis in the patient. This assessment, which will be used to determine eligibility for continuing treatment, should be conducted and submitted after the patient has completed 8 weeks of the initial treatment course and no later than 2 weeks prior to the patient completing the PBS-subsidised initial treatment course, to avoid an interruption to supply. Where</p>	Compliance with Authority Required procedures
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			a histologic assessment is not undertaken and the results submitted, the patient will be not be eligible for ongoing treatment.	
	C12938	P12938	<p>Eosinophilic oesophagitis Initial treatment - Induction of remission Patient must have a history of symptoms of oesophageal dysfunction; AND Patient must have eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy confirming the presence of at least 15 eosinophils in at least one high power field (hpf); corresponding to approximately 60 eosinophils per mm<sup>2</sup>hpf; AND Patient must not receive more than 90 days of treatment under this restriction. Must be treated by a gastroenterologist. Applications for treatment of this condition must be received within 12 weeks of biopsy. Symptoms of oesophageal dysfunction include at least one of the following: dysphasia, odynophagia, transient or self-cleared food impaction, chest pain, epigastric discomfort, vomiting/regurgitation. Diagnostic sensitivity increases with the number of biopsies and is optimised after taking at least eight biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction). A histologic assessment of the oesophageal biopsy should be planned for approximately 8 weeks after the initiation of the first PBS-subsidised treatment with this drug under this restriction, and no later than 2 weeks prior to the patient completing the PBS-subsidised initial treatment course, to determine the patient's eligibility for continuing therapy and to avoid an interruption to supply.</p>	Compliance with Authority Required procedures
	C13968	P13968	<p>Eosinophilic oesophagitis Subsequent continuing treatment - Maintenance of remission Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND The condition must not have progressed while being treated with this drug. Must be treated by a gastroenterologist or in consultation with a gastroenterologist.</p>	Compliance with Authority Required procedures

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

	C14608	P14608	<p>Eosinophilic oesophagitis Initial treatment - Induction of remission Patient must have a history of symptoms of oesophageal dysfunction; AND Patient must have eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy confirming the presence of at least 15 eosinophils in at least one high power field (hpf); corresponding to approximately 60 eosinophils per mm<sup>2</sup>hpf; AND Patient must not receive more than 90 days of treatment under this restriction. Must be treated by a prescriber who is either: (i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis. Applications for treatment of this condition must be received within 12 weeks of biopsy. Symptoms of oesophageal dysfunction include at least one of the following: dysphasia, odynophagia, transient or self-cleared food impaction, chest pain, epigastric discomfort, vomiting/regurgitation. Diagnostic sensitivity increases with the number of biopsies and can be optimised, where necessary, by taking at least eight biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least</p>	Compliance with Authority Required procedures
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			<p>5 cm above the gastroesophageal junction).</p> <p>After prescribing the Initial induction treatment with budesonide, a histologic assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing therapy.</p> <p>The histologic assessment should be conducted no later than 2 weeks prior to completing the PBS-subsidised First continuing maintenance treatment course to avoid an interruption of supply for continuing therapy.</p>	
	C14610	P14610	<p>Eosinophilic oesophagitis</p> <p>First continuing treatment - until remission is confirmed</p> <p>Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug for this condition; AND</p> <p>Patient must not receive more than 36 weeks of treatment under this restriction.</p> <p>Must be treated by a prescriber who is either: (i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis, (iv) medical practitioner who has consulted at least one of the above-mentioned prescriber types.</p> <p>Histologic assessment should be based on the peak eosinophils count derived, where necessary, from the evaluation of at least eight oesophageal biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction).</p> <p>The histologic assessment should, where possible, be performed by, or in consultation with, the same physician or surgeon who confirmed the patient's diagnosis of eosinophilic oesophagitis. This assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing treatment. The histologic assessment should be conducted no later than 2 weeks prior to the patient completing the PBS-subsidised First continuing treatment course to avoid an interruption of supply for continuing therapy. Where a histologic assessment is not undertaken, the patient will not be eligible for ongoing treatment.</p> <p>The result of the histological assessment must be documented in the patient's medical records.</p> <p>First application for the subsequent continuing treatment of this condition must be received within 12 weeks of the histologic assessment.</p>	Compliance with Authority Required procedures
	C14619	P14619	<p>Eosinophilic oesophagitis</p> <p>Subsequent continuing treatment - Maintenance of remission</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND</p> <p>Patient must have documented evidence of having achieved histologic remission while receiving Initial and First continuing PBS-subsidised treatment with this drug for this condition, defined as a peak eosinophil count of less than 5 eosinophils per high power field (hpf), corresponding to less than 16 eosinophils per mm<sup>2</sup>hpf on oesophageal biopsy; AND</p> <p>The condition must not have progressed while being treated with this drug.</p> <p>Must be treated by a prescriber who is either: (i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis, (iv) medical practitioner who has consulted at least one of the above-mentioned prescriber types.</p> <p>Histologic assessment should be based on the peak eosinophils count derived, where necessary, from the evaluation of at least eight oesophageal biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction).</p> <p>The histologic assessment should, where possible, be performed by, or in consultation with, the same physician or surgeon who confirmed the patient's diagnosis of eosinophilic oesophagitis. This assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing treatment. The histologic assessment should be</p>	Compliance with Authority Required procedures

				<p>conducted no later than 2 weeks prior to the patient completing the PBS-subsidised First continuing treatment course to avoid an interruption of supply for continuing therapy. Where a histologic assessment is not undertaken, the patient will not be eligible for ongoing treatment.</p> <p>The result of the histological assessment must be documented in the patient's medical records.</p> <p>First application for the subsequent continuing treatment of this condition must be received within 12 weeks of the histologic assessment.</p>	
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**[245] Schedule 4, Part 1, entry for Certolizumab pegol**

**(a) omit:**

	C8627	P8627		<p>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.</p>	Compliance with Authority Required procedures
	C8679	P8679		<p>Severe active rheumatoid arthritis Continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and</p>	Compliance with Written Authority Required procedures

			<p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>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.</p>	
	C8706	P8706	<p>Severe active rheumatoid arthritis</p> <p>Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months - balance of supply).</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR</p> <p>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 18 to 20 weeks treatment, depending on the dosage regimen; OR</p> <p>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) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; AND</p> <p>The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.</p>	Compliance with Authority Required procedures

**(b)** omit:

	C11686	P11686	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>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</p>	Compliance with Written Authority Required procedures
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			<p>active major joints; 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.  Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.  If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.  The authority application must be made in writing and must include:  (1) a completed authority prescription form(s); and  (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.  It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.  To demonstrate a response to treatment the application must be accompanied with the assessment of response from the 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.</p>	
	C11748	P11748	<p>Severe active rheumatoid arthritis  Initial treatment - Initial 1 (new patient)  Must be treated by a rheumatologist; OR  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.  Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR  Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a</p>	Compliance with Written Authority Required procedures

			<p>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</p> <p>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</p> <p>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</p> <p>Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>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.</p> <p>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 including severity and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:</p> <p>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</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>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.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p>	
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			<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>	
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(c) omit:

	C14113	P14113	<p>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 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-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.</p>	Compliance with Written Authority Required procedures
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			<p>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.</p> <p>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.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>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.</p>	
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**(d)** insert in numerical order after existing text:

	C14493	P14493	<p>Severe active rheumatoid arthritis</p> <p>First continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>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</p>	Compliance with Written Authority Required procedures
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			<p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>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.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>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.</p>	
	C14499	P14499	<p>Severe active rheumatoid arthritis</p> <p>Subsequent continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR</p> <p>Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14499



			<p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>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.</p>	
	C14507	P14507	<p>Severe active rheumatoid arthritis</p> <p>First continuing treatment - balance of supply</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment.</p>	Compliance with Authority Required procedures
	C14542	P14542	<p>Severe active rheumatoid arthritis</p> <p>Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR</p> <p>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 18 to 20 weeks treatment, depending on the dosage regimen; OR</p> <p>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) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; AND</p> <p>The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.</p>	Compliance with Authority Required procedures
	C14571	P14571	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>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 at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>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/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of</p>	Compliance with Written Authority Required procedures

			<p>at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (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 contraindicated according to the relevant TGA-approved Product Information/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 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.  Patient must be at least 18 years of age.  If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.  The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.  The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.  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 including severity and dose for each DMARD must be provided in the authority application.  The following criteria indicate failure to achieve an adequate response to DMARD treatment 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 and/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 4 weeks old at the time of initial application.  If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response 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; 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).</p>	
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			<p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>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.</p> <p>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.</p>	
	C14591	P14591	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR</p> <p>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</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Patients who have received PBS-subsidised 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.</p> <p>Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.</p> <p>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.</p>	Compliance with Written Authority Required procedures

			<p>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.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>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.</p> <p>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.</p>	
	C14622	P14622	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>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).</p> <p>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>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.</p>	Compliance with Written Authority Required procedures

			<p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>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.</p> <p>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.</p> <p>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.</p>	
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**[246] Schedule 4, Part 1, entry for Donepezil**

*omit:*

	C10099		<p>Mild to moderately severe Alzheimer disease</p> <p>Initial 2</p> <p>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND</p> <p>The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.</p> <p>Patients who qualify under this criterion are from 1 or more of the following groups:</p> <ol style="list-style-type: none"> <li>(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;</li> <li>(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;</li> <li>(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;</li> <li>(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;</li> <li>(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;</li> <li>(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.</li> </ol> <p>Application through this treatment restriction must be made in writing.</p> <p>Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month's therapy and sufficient repeats to complete 6 months' initial treatment with this strength of this drug will be authorised under this restriction.</p> <p>Where no prior approval has been issued before this application, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.</p>	Compliance with Written Authority Required procedures
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	C10100			<p>Mild to moderately severe Alzheimer disease</p> <p>Initial 2</p> <p>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more; AND</p> <p>The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.</p> <p>Application through this treatment restriction must be made in writing.</p> <p>Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month's therapy and sufficient repeats to complete 6 months' initial treatment with this strength of this drug will be authorised under this restriction.</p> <p>Where no prior approval has been issued before this application, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.</p>	Compliance with Written Authority Required procedures
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**[247] Schedule 4, Part 1, entry for Empagliflozin**

*insert in numerical order after existing text:*

	C14471			<p>Chronic heart failure</p> <p>Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug; AND</p> <p>Patient must have a documented left ventricular ejection fraction (LVEF) of greater than 40%; AND</p> <p>Patient must have documented evidence of structural changes in the heart on echocardiography that would be expected to cause diastolic dysfunction (e.g. left ventricular hypertrophy); AND</p> <p>Patient must have documented evidence of at least one of the following: (i) diastolic dysfunction with high filling pressure on echocardiography, stress echocardiography or cardiac catheterisation; (ii) hospitalisation for heart failure in the 12 months prior to initiating treatment with this drug; (iii) requirement for intravenous diuretic therapy in the 12 months prior to initiating treatment with this drug; (iv) elevated N-terminal pro brain natriuretic peptide (NT-proBNP) levels in the absence of another cause; AND</p> <p>Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14471
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**[248] Schedule 4, Part 1, entry for Etanercept**

**(a)** *omit:*

	C7276	P7276		<p>Severe active rheumatoid arthritis</p> <p>Subsequent continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must be aged 18 years or older.</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition; AND</p> <p>Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this</p>	Compliance with Authority Required procedures - Streamlined Authority Code 7276
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			<p>restriction.  For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.  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).  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.  The 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 under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
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**(b) omit:**

	C8638	P8638	<p>Severe active rheumatoid arthritis  Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply  Must be treated by a rheumatologist; OR  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR  Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND  The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p>	Compliance with Authority Required procedures
	C8662	P8662	<p>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 first continuing treatment restriction to complete 24 weeks treatment; OR</p>	Compliance with Authority Required procedures

			<p>Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.</p>	
	C8692	P8692	<p>Severe active rheumatoid arthritis Subsequent 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 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 subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	Compliance with Written Authority Required procedures
	C8718	P8718	<p>Severe active rheumatoid arthritis First Continuing treatment</p>	Compliance with Written Authority Required



			<p>Must be treated by a rheumatologist; OR          Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.          Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND          Patient must have demonstrated an adequate response to treatment with this drug; AND          Patient must not receive more than 24 weeks of treatment 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).          Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.          The authority application must be made in writing and must include:          (1) a completed authority prescription form(s); and          (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.          It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.          Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.          If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.          If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	procedures
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(c) omit:

	C12260	P12260	<p>Severe chronic plaque psoriasis          Initial 1 treatment (Whole body) - biological medicine-naive patient          Must be treated by a dermatologist.          Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; AND          The treatment must be as systemic monotherapy; OR          The treatment must be in combination with methotrexate; AND          Patient must have lesions present for at least 6 months from the time of initial diagnosis; AND</p>	Compliance with Written Authority Required procedures
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			<p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND  Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.  Patient must be under 18 years of age.</p> <p>Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.  Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.  Details of the accepted toxicities including severity can be found on the Services Australia website.  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).</p> <p>The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:  (a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.  A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. State in this authority application, each of:  (i) the name of each prior therapy trialled that meets the above requirements - state at least 2;  (ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);  (iii) the PASI score that followed each prior therapy trialled;  (iv) the date the PASI scores were determined</p> <p>State a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.</p>	
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**(d)** omit:

	C12262	P12262	<p>Severe chronic plaque psoriasis  Initial 2 treatment (Face, hand, foot) - Change of treatment  Must be treated by a dermatologist.  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 more than once during the current treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND  The treatment must be as systemic monotherapy; OR  The treatment must be in combination with methotrexate; AND  Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.  Patient must be under 18 years of age.</p>	Compliance with Written Authority Required procedures
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			<p>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:</p> <p>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or</p> <p>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.</p> <p>In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:</p> <p>(i) there is an absence of an adequate response to that treatment; or</p> <p>(ii) there was an intolerance to that treatment; or</p> <p>(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p>	
	C12265	P12265	<p>Severe chronic plaque psoriasis</p> <p>Completion of course - treatment covering weeks 16 to 24 (Whole body)</p> <p>Must be treated by a dermatologist; AND</p> <p>Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.</p> <p>The treatment must be as systemic monotherapy; OR</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must be assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose; AND</p> <p>Patient must have demonstrated an adequate response to treatment; AND</p> <p>Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>An adequate response to treatment is defined as:</p> <p>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.</p> <p>The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.</p>	Compliance with Written Authority Required procedures
	C12266	P12266	<p>Severe chronic plaque psoriasis</p> <p>Completion of course - treatment covering weeks 16 to 24 (Face, hand, foot)</p> <p>Must be treated by a dermatologist; AND</p> <p>Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.</p> <p>The treatment must be as systemic monotherapy; OR</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must be assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this</p>	Compliance with Written Authority Required procedures

			<p>biological medicine, but within 8 weeks of the last administered dose; AND  Patient must have demonstrated an adequate response to treatment; AND  Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.  The authority application must be made in writing and must include:  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.</p>	
	C12287	P12287	<p>Severe chronic plaque psoriasis  Initial 2 treatment (Whole body) - Change of treatment  Must be treated by a dermatologist.  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 more than once during the current treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND  The treatment must be as systemic monotherapy; OR  The treatment must be in combination with methotrexate; AND  Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.  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).  An adequate response to treatment is defined as:  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:  (i) there is an absence of an adequate response to that treatment; or  (ii) there was an intolerance to that treatment; or  (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.</p>	Compliance with Written Authority Required procedures
	C12289	P12289	<p>Severe chronic plaque psoriasis  Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient  Must be treated by a dermatologist.</p>	Compliance with Written Authority Required procedures

			<p>Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; AND  The treatment must be as systemic monotherapy; OR  The treatment must be in combination with methotrexate; AND  Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis; AND  Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND  Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.  Patient must be under 18 years of age.  Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.  Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.  Details of the accepted toxicities including severity can be found on the Services Australia website.  The authority application must be made in writing and must include:  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:  (a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or  (b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy  State in this authority application, each of:  (i) the name of each prior therapy trialled that meets the above requirements - state at least 2;  (ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);  (iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;  (iv) the dates that response assessments were determined  State in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:  (v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);  (vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.  Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.</p>	
	C12327	P12327	<p>Severe chronic plaque psoriasis  Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years</p>	Compliance with Written Authority Required procedures

			<p>Must be treated by a dermatologist.</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle; AND</p> <p>The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; OR</p> <p>The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot'; AND</p> <p>Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; OR</p> <p>The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND</p> <p>The treatment must be as systemic monotherapy; OR</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.</p> <p>Patient must be under 18 years of age.</p> <p>The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p>	
	C12434	P12434	<p>Severe chronic plaque psoriasis</p> <p>Initial 4 - Re-treatment (face, hand, foot)</p> <p>Must be treated by a dermatologist.</p> <p>The treatment must be as systemic monotherapy; OR</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot.</p> <p>Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) all PASI sub-measures (redness, thickness, scaling) are rated as 'moderate' to 'severe', (ii) at least 2 of the 3 PASI sub-measures are rated as 'severe' to 'very severe', (iii) the skin area affected has increased by at least 50% since the last administered dose, (iv) the skin area affected is at least 30% of the total skin area of the face/hand/foot.</p> <p>Patient must not have failed more than once to achieve an adequate response with etanercept; AND</p> <p>Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.</p> <p>Patient must be under 18 years of age.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.</p>	Compliance with Written Authority Required procedures
	C12457	P12457	Severe chronic plaque psoriasis	Compliance with Written

			<p>Initial 4 - Re-treatment (Whole body)          Must be treated by a dermatologist.          The treatment must be as systemic monotherapy; OR          The treatment must be in combination with methotrexate; AND          Patient must have a documented history of severe chronic plaque psoriasis of the whole body.          Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) a disease flare where the PASI score has worsened (increased) by at least 50%, (ii) the current PASI score has returned above 15.          Patient must not have failed more than once to achieve an adequate response with etanercept; AND          Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.          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).          Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.</p>	Authority Required procedures
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(e) omit:

	C13542	P13542	<p>Severe active rheumatoid arthritis          Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)          Must be treated by a rheumatologist; OR          Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.          Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND          Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND          Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND          Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND          The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR          The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND          The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND          Patient must not receive more than 16 weeks of treatment under this restriction.          Patient must be at least 18 years of age.          Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).          All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.          If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.          Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be</p>	Compliance with Written Authority Required procedures
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			<p>determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>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 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.</p> <p>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.</p> <p>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.</p>	
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(f) omit:

	C13707	P13707	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>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</p> <p>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</p> <p>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</p>	Compliance with Written Authority Required procedures
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			<p>application; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>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.</p> <p>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 including severity and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:</p> <p>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</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>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.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>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 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.</p> <p>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</p>	
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			<p>the necessity for permanent withdrawal of treatment.</p> <p>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.</p>	
	C14108	P14108	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR</p> <p>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</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>Patients who have received PBS-subsidised 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.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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</p>	Compliance with Written Authority Required procedures

				<p>for permanent withdrawal of treatment.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>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.</p>	
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**(g)** *insert in numerical order after existing text:*

	C14483	P14483		<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR</p> <p>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</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Patients who have received PBS-subsidised 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.</p> <p>Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted</p>	Compliance with Written Authority Required procedures
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			<p>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.</p> <p>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.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>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.</p> <p>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.</p>	
	C14486	P14486	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>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).</p> <p>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p>	Compliance with Written Authority Required procedures

			<p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>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.</p> <p>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.</p> <p>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.</p>	
	C14488	P14488	<p>Severe active rheumatoid arthritis</p> <p>Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>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</p> <p>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</p> <p>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</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p>	Compliance with Authority Required procedures
	C14493	P14493	<p>Severe active rheumatoid arthritis</p> <p>First continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as:</p>	Compliance with Written Authority Required procedures

			<p>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).  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; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within 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 has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
	C14498	P14498	<p>Severe active rheumatoid arthritis  Initial treatment - Initial 1 (new patient)  Must be treated by a rheumatologist; OR  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.  Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (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/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (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</p>	Compliance with Written Authority Required procedures

			<p>to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/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</p> <p>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</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>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, however the time on treatment must be at least 6 months.</p> <p>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 including severity and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>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 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p>	
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	C14499	P14499	<p>Severe active rheumatoid arthritis  Subsequent continuing treatment  Must be treated by a rheumatologist; OR  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR  Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment under this restriction.  Patient must be at least 18 years of age.  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).  The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.  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.  If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14499</p>
	C14507	P14507	<p>Severe active rheumatoid arthritis  First 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 first continuing treatment restriction to complete 24 weeks treatment; AND</p>	<p>Compliance with Authority Required procedures</p>



			The treatment must provide no more than the balance of up to 24 weeks treatment.	
	C14508	P14508	<p>Severe chronic plaque psoriasis  Completion of course - treatment covering weeks 16 to 24 (Face, hand, foot)  Must be treated by a dermatologist; AND  Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.  The treatment must be as systemic monotherapy; OR  The treatment must be in combination with methotrexate; AND  Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose; AND  Patient must have demonstrated an adequate response to treatment; AND  Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  The assessment of response to treatment must be documented in the patient's medical records.  The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14508
	C14509	P14509	<p>Severe chronic plaque psoriasis  Completion of course - treatment covering weeks 16 to 24 (Whole body)  Must be treated by a dermatologist; AND  Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.  The treatment must be as systemic monotherapy; OR  The treatment must be in combination with methotrexate; AND  Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose; AND  Patient must have demonstrated an adequate response to treatment; AND  Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.  An adequate response to treatment is defined as:  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  The assessment of response to treatment must be documented in the patient's medical records.  The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14509
	C14513	P14513	<p>Severe chronic plaque psoriasis  Initial 1 treatment (Whole body) - biological medicine-naive patient  Must be treated by a dermatologist.  Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; AND</p>	Compliance with Authority Required procedures

			<p>The treatment must be as systemic monotherapy; OR</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must have lesions present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND</p> <p>Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.</p> <p>Patient must be under 18 years of age.</p> <p>Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be documented in the patient's medical records.</p> <p>Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be documented in the patient's medical records.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:</p> <p>(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.</p> <p>A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of:</p> <p>(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;</p> <p>(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);</p> <p>(iii) the PASI score that followed each prior therapy trialled;</p> <p>(iv) the date the PASI scores were determined.</p> <p>Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.</p>	
	C14552	P14552	<p>Severe chronic plaque psoriasis</p> <p>Initial 2 treatment (Face, hand, foot) - Change of treatment</p> <p>Must be treated by a dermatologist.</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>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</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND</p> <p>The treatment must be as systemic monotherapy; OR</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.</p> <p>Patient must be under 18 years of age.</p> <p>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:</p> <p>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and</p>	Compliance with Authority Required procedures

			<p>scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.</p> <p>In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:  (i) there is an absence of an adequate response to that treatment; or  (ii) there was an intolerance to that treatment; or  (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.</p> <p>The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.</p>	
	C14553	P14553	<p>Severe chronic plaque psoriasis  Initial 4 - Re-treatment (Whole body)  Must be treated by a dermatologist.</p> <p>The treatment must be as systemic monotherapy; OR  The treatment must be in combination with methotrexate; AND  Patient must have a documented history of severe chronic plaque psoriasis of the whole body.  Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) a disease flare where the PASI score has worsened (increased) by at least 50%, (ii) the current PASI score has returned above 15.  Patient must not have failed more than once to achieve an adequate response with etanercept; AND  Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.  Patient must be under 18 years of age.  Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.</p>	Compliance with Authority Required procedures
	C14554	P14554	<p>Severe chronic plaque psoriasis  Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient  Must be treated by a dermatologist.</p> <p>Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; AND  The treatment must be as systemic monotherapy; OR  The treatment must be in combination with methotrexate; AND  Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis; AND  Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND  Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.  Patient must be under 18 years of age.  Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be documented in the patient's medical records.  Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a</p>	Compliance with Authority Required procedures

			<p>severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be documented in the patient's medical records.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:</p> <p>(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or</p> <p>(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy</p> <p>Provide in this authority application, and document in the patient's medical records, each of:</p> <p>(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;</p> <p>(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);</p> <p>(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;</p> <p>(iv) the dates that response assessments were determined.</p> <p>Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:</p> <p>(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);</p> <p>(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.</p> <p>Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.</p>	
	C14576	P14576	<p>Severe chronic plaque psoriasis</p> <p>Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years</p> <p>Must be treated by a dermatologist.</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle; AND</p> <p>The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; OR</p> <p>The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot'; AND</p> <p>Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; OR</p> <p>The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND</p> <p>The treatment must be as systemic monotherapy; OR</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.</p> <p>Patient must be under 18 years of age.</p> <p>The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.</p>	Compliance with Authority Required procedures

	C14577	P14577	<p>Severe chronic plaque psoriasis Initial 4 - Re-treatment (face, hand, foot) Must be treated by a dermatologist. The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate; AND Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot. Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) all PASI sub-measures (redness, thickness, scaling) are rated as 'moderate' to 'severe', (ii) at least 2 of the 3 PASI sub-measures are rated as 'severe' to 'very severe', (iii) the skin area affected has increased by at least 50% since the last administered dose, (iv) the skin area affected is at least 30% of the total skin area of the face/hand/foot. Patient must not have failed more than once to achieve an adequate response with etanercept; AND Patient must not receive more than 16 weeks of treatment with etanercept under this restriction. Patient must be under 18 years of age. Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.</p>	Compliance with Authority Required procedures
	C14581	P14581	<p>Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (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/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (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 contraindicated according to the relevant TGA-approved Product Information/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 of the contraindications/severe intolerances; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided</p>	Compliance with Authority Required procedures

			<p>at the time of the application, if applicable, and documented in the patient's medical records.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>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, however the time on treatment must be at least 6 months.</p> <p>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 including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.</p> <p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>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 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>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.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:</p> <p>(a) the active joint count, ESR and/or CRP result and date of results;</p> <p>(b) details of prior treatment, including dose and date/duration of treatment.</p> <p>(c) If applicable, details of any contraindications/intolerances.</p> <p>(d) If applicable, the maximum tolerated dose of methotrexate.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>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.</p> <p>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.</p>	
	C14582	P14582	Severe active rheumatoid arthritis	Compliance with

			<p>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 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/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 at least 18 years of age.  Patients who have received PBS-subsidised 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.  Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.  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).  The assessment of response to treatment must be documented in the patient's medical records.  An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a 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.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive</p>	Authority Required procedures
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			<p>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.</p>	
	C14600	P14600	<p>Severe chronic plaque psoriasis  Initial 2 treatment (Whole body) - Change of treatment  Must be treated by a dermatologist.  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 more than once during the current treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND  The treatment must be as systemic monotherapy; OR  The treatment must be in combination with methotrexate; AND  Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.  Patient must be under 18 years of age.  An adequate response to treatment is defined as:  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:  (i) there is an absence of an adequate response to that treatment; or  (ii) there was an intolerance to that treatment; or  (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.  The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.</p>	Compliance with Authority Required procedures
	C14603	P14603	<p>Severe active rheumatoid 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 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/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND  The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND  Patient must not receive more than 16 weeks of treatment under this restriction.</p>	Compliance with Authority Required procedures



			<p>Patient must be at least 18 years of age.</p> <p>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).</p> <p>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>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.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:</p> <p>(a) the active joint count, ESR and/or CRP result and date of result;</p> <p>(b) the most recent biological agent and the date of the last continuing prescription.</p> <p>(c) If applicable, the new baseline scores.</p> <p>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.</p> <p>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.</p> <p>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.</p>	
	C14629	P14629	<p>Severe active rheumatoid arthritis</p> <p>First continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14629

				<p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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 assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>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.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>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.</p>	
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**[249] Schedule 4, Part 1, entry for Ezetimibe and rosuvastatin**

*insert in the column headed "Purposes Code" for the Circumstances Code "C7958": P7958*

**[250] Schedule 4, Part 1, entry for Fremanezumab**

*substitute:*

Fremanezumab	C14472	P14472		<p>Treatment-resistant migraine Initial treatment Must be treated by a neurologist; AND Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication. Patient must have experienced at least 8 migraine headache days per month, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition; AND Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition; AND Patient must be appropriately managed by their practitioner for medication overuse headache, prior to initiation of treatment with this drug. Patient must be at least 18 years of age. Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate. Patient must have the number of migraine headache days per month documented in their medical records.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14472
	C14563	P14563		<p>Treatment-resistant migraine Continuing treatment Must be treated by a neurologist; OR Must be treated by a general practitioner in consultation with a neurologist; AND Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14563

				<p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have achieved and maintained at least 50% reduction from baseline in the number of migraine headache days per month; AND  Patient must continue to be appropriately managed for medication overuse headache.  Patient must have the number of migraine headache days per month documented in their medical records.</p>	
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**[251] Schedule 4, Part 1, entry for Galantamine**

*omit:*

	C10099			<p>Mild to moderately severe Alzheimer disease  Initial 2  Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND  The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND  The treatment must be the sole PBS-subsidised therapy for this condition.  A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.  Patients who qualify under this criterion are from 1 or more of the following groups:  (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;  (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;  (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;  (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;  (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;  (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.  Application through this treatment restriction must be made in writing.  Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month's therapy and sufficient repeats to complete 6 months' initial treatment with this strength of this drug will be authorised under this restriction.  Where no prior approval has been issued before this application, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.</p>	Compliance with Written Authority Required procedures
	C10100			<p>Mild to moderately severe Alzheimer disease  Initial 2  Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more; AND  The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND  The treatment must be the sole PBS-subsidised therapy for this condition.  The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.  Application through this treatment restriction must be made in writing.</p>	Compliance with Written Authority Required procedures

			<p>Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month's therapy and sufficient repeats to complete 6 months' initial treatment with this strength of this drug will be authorised under this restriction.</p> <p>Where no prior approval has been issued before this application, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.</p>	
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**[252] Schedule 4, Part 1, omit entry for Gentamicin**

**[253] Schedule 4, Part 1, entry for Golimumab**

**(a) omit:**

	C8641	P8641	<p>Severe active rheumatoid arthritis Continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment 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). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent</p>	Compliance with Written Authority Required procedures
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			<p>withdrawal of treatment.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>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.</p>	
	C8642	P8642	<p>Severe active rheumatoid arthritis</p> <p>Continuing Treatment - balance of supply</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.</p>	Compliance with Authority Required procedures
	C8713	P8713	<p>Severe active rheumatoid arthritis</p> <p>Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>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</p> <p>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</p> <p>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</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p>	Compliance with Authority Required procedures

**(b)** omit:

	C11779	P11779	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>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</p>	Compliance with Written Authority Required procedures
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			<p>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</p> <p>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</p> <p>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</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.</p> <p>Patient must be aged 18 years or older.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>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.</p> <p>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 including severity and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:</p> <p>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</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>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.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>The authority application must be made in writing and must include:</p>	
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			<p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>	
	C11780	P11780	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>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</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.</p> <p>Patient must be aged 18 years or older.</p> <p>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).</p> <p>All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>The authority application must be made in writing and must include:</p>	Compliance with Written Authority Required procedures

			<p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>	
	C14171	P14171	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR</p> <p>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</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.</p> <p>Patient must be aged 18 years or older.</p> <p>Patients who have received PBS-subsidised 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.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>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-</p>	Compliance with Written Authority Required procedures



			<p>subsidised treatment with this drug, within the timeframes specified below.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>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.</p>	
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(c) *insert in numerical order after existing text:*

	C14488	P14488	<p>Severe active rheumatoid arthritis</p> <p>Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>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</p> <p>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</p> <p>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</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p>	Compliance with Authority Required procedures
	C14507	P14507	<p>Severe active rheumatoid arthritis</p> <p>First continuing treatment - balance of supply</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction</p>	Compliance with Authority Required procedures

			to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment.	
	C14519	P14519	<p>Severe active rheumatoid arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment 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 at least 18 years of age. 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). 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; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within 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 has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	Compliance with Written Authority Required procedures
	C14556	P14556	<p>Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24</p>	Compliance with Written Authority Required

			<p>months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR</p> <p>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</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.</p> <p>Patient must be at least 18 years of age.</p> <p>Patients who have received PBS-subsidised 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.</p> <p>Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p>	procedures
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			<p>(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).</p> <p>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.</p> <p>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.</p>	
	C14557	P14557	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.</p> <p>Patient must be at least 18 years of age.</p> <p>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).</p> <p>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>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</p>	Compliance with Written Authority Required procedures

			<p>continuing restriction.</p> <p>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.</p> <p>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.</p>	
	C14604	P14604	<p>Severe active rheumatoid arthritis</p> <p>Subsequent continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR</p> <p>Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.</p> <p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>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.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>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.</p> <p>If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14604</p>
	C14626	P14626	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p>	<p>Compliance with Written Authority Required</p>

			<p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>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 at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>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/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>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 contraindicated according to the relevant TGA-approved Product Information/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</p> <p>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</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.</p> <p>Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>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, however the time on treatment must be at least 6 months.</p> <p>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 including severity and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p>	procedures
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			<p>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 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>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.</p> <p>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.</p>	
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**[254] Schedule 4, Part 1, entry for Infliximab**

(a) *omit:*

	C11828	P11828	<p>Severe active rheumatoid arthritis</p> <p>Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; OR</p> <p>Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p>	Compliance with Written Authority Required procedures
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			<p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) 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).</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>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 within 4 weeks prior to completing their current course of treatment.</p> <p>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.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>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.</p> <p>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.</p>	
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**(b)** insert in numerical order after existing text:

	C14504		<p>Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; OR Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. 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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14504
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			<p>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).  The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.  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 date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab.  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.  If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.  If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p>	
	C14505		<p>Severe active rheumatoid arthritis  Subsequent continuing treatment  Must be treated by a rheumatologist; OR  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR  Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; OR  Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment under this restriction; AND  The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.  Patient must be at least 18 years of age.  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%:</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14505</p>

			<p>(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 assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.  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 date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab.  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.  If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.  If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p>	
	C14515	P14515	<p>Severe active rheumatoid arthritis  Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form  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 (in any form) 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; OR  Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form; AND  The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; AND  Patient must not receive more than 24 weeks of treatment under this restriction.  Patient must be at least 18 years of age.  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).  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:</p>	Compliance with Written Authority Required procedures

			<p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>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.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>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.</p> <p>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.</p>	
	C14585		<p>Severe active rheumatoid arthritis</p> <p>First continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR</p> <p>Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.</p> <p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14585

			<p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>The date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab.</p> <p>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.</p> <p>If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.</p>	
	C14638		<p>Severe active rheumatoid arthritis</p> <p>First continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR</p> <p>Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.</p> <p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>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.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>The date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab.</p> <p>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.</p> <p>If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14638</p>

				intolerance, details must be documented in the patient's medical records.	
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**[255] Schedule 4, Part 1, entry for Memantine**

*omit:*

	C10098			<p>Moderately severe Alzheimer disease Initial 2 Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs. Patients who qualify under this criterion are from 1 or more of the following groups: (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background; (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate; (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test; (4) Intellectual (developmental or acquired) disability, eg Down's syndrome; (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test; (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment. Application through this treatment restriction must be made in writing. Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month's therapy and sufficient repeats to complete 6 months' initial treatment with this strength of this drug will be authorised under this restriction. Where no prior approval has been issued before this application, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.</p>	Compliance with Written Authority Required procedures
	C10184			<p>Moderately severe Alzheimer disease Initial 2 Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14. Application through this treatment restriction must be made in writing. Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month's therapy and sufficient repeats to complete 6 months' initial treatment with this strength of this drug will be authorised under this restriction. Where no prior approval has been issued before this application, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.</p>	Compliance with Written Authority Required procedures

**[256] Schedule 4, Part 1, entry for Rivastigmine**

*omit:*

	C10099		<p>Mild to moderately severe Alzheimer disease Initial 2 Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs. Patients who qualify under this criterion are from 1 or more of the following groups: (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background; (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate; (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test; (4) Intellectual (developmental or acquired) disability, eg Down's syndrome; (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test; (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment. Application through this treatment restriction must be made in writing. Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month's therapy and sufficient repeats to complete 6 months' initial treatment with this strength of this drug will be authorised under this restriction. Where no prior approval has been issued before this application, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.</p>	Compliance with Written Authority Required procedures
	C10100		<p>Mild to moderately severe Alzheimer disease Initial 2 Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more; AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND The treatment must be the sole PBS-subsidised therapy for this condition. The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified. Application through this treatment restriction must be made in writing. Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month's therapy and sufficient repeats to complete 6 months' initial treatment with this strength of this drug will be authorised under this restriction. Where no prior approval has been issued before this application, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.</p>	Compliance with Written Authority Required procedures

**[257] Schedule 4, Part 1, entry for Tocilizumab**

(a) *omit:*

	C8627	P8627	<p>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.</p>	Compliance with Authority Required procedures
	C8633	P8633	<p>Severe active rheumatoid arthritis Continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will</p>	Compliance with Written Authority Required procedures

			not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C8638	P8638	Severe active rheumatoid arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	Compliance with Authority Required procedures

**(b) omit:**

	C11689	P11689	Severe active rheumatoid arthritis Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.	Compliance with Written Authority Required procedures
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			<p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>	
	C11781	P11781	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>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</p> <p>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</p> <p>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</p>	Compliance with Written Authority Required procedures

			<p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>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.</p> <p>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 including severity and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:</p> <p>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</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>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.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>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.</p> <p>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.</p>	
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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 further PBS-subsidised treatment with this drug for this condition.	
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(c) omit:

	C14056	P14056		<p>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-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to</p>	Compliance with Written Authority Required procedures
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				<p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>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.</p>	
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**(d)** insert in numerical order after existing text:

	C14483	P14483		<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR</p> <p>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</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Patients who have received PBS-subsidised 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.</p> <p>Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.</p>	Compliance with Written Authority Required procedures
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			<p>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.</p> <p>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.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>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.</p> <p>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.</p>	
	C14485	P14485	<p>Severe active rheumatoid arthritis  Subsequent continuing treatment  Must be treated by a rheumatologist; OR  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR  Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment under this restriction.  Patient must be at least 18 years of age.  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).  The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14485

			<p>weeks old at the time of the authority application.</p> <p>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.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority approval is required for each strength requested.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>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.</p>	
	C14486	P14486	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>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).</p> <p>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p>	Compliance with Written Authority Required procedures

			<p>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.</p> <p>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.</p> <p>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.</p>	
	C14488	P14488	<p>Severe active rheumatoid arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p>	Compliance with Authority Required procedures
	C14493	P14493	<p>Severe active rheumatoid arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. 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</p>	Compliance with Written Authority Required procedures

			<p>limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response 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; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within 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 has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
	C14498	P14498	<p>Severe active rheumatoid arthritis  Initial treatment - Initial 1 (new patient)  Must be treated by a rheumatologist; OR  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.  Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (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/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (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 contraindicated according to the relevant TGA-approved Product Information/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.</p>	Compliance with Written Authority Required procedures



			<p>Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>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, however the time on treatment must be at least 6 months.</p> <p>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 including severity and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>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 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>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.</p> <p>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.</p>	
	C14499	P14499	<p>Severe active rheumatoid arthritis</p> <p>Subsequent continuing treatment</p>	<p>Compliance with Authority Required</p>

			<p>Must be treated by a rheumatologist; OR          Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.          Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR          Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND          Patient must have demonstrated an adequate response to treatment with this drug; AND          Patient must not receive more than 24 weeks of treatment under this restriction.          Patient must be at least 18 years of age.          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).          The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.          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.          If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.          If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	<p>procedures -          Streamlined Authority          Code 14499</p>
	C14507	P14507	<p>Severe active rheumatoid arthritis          First 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 first continuing treatment restriction to complete 24 weeks treatment; AND          The treatment must provide no more than the balance of up to 24 weeks treatment.</p>	<p>Compliance with          Authority Required          procedures</p>
	C14621	P14621	<p>Severe active rheumatoid arthritis          Subsequent continuing treatment          Must be treated by a rheumatologist; OR          Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.          Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR</p>	<p>Compliance with          Authority Required          procedures -          Streamlined Authority          Code 14621</p>

			<p>Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>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.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority approval is required for each strength requested.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>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.</p>	
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**[258] Schedule 4, Part 1, entry for Tofacitinib**

**(a) omit:**

	C8627	P8627	<p>Severe active rheumatoid arthritis</p> <p>Continuing Treatment - balance of supply.</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.</p>	Compliance with Authority Required procedures
	C8638	P8638	<p>Severe active rheumatoid arthritis</p> <p>Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of</p>	Compliance with Authority Required procedures

			<p>supply</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>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</p> <p>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</p> <p>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</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p>	
	C8725	P8725	<p>Severe active rheumatoid arthritis</p> <p>Continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	Compliance with Written Authority Required procedures

				<p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>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.</p>	
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**(b) omit:**

	C11689	P11689		<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>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</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>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).</p> <p>All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>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.</p>	Compliance with Written Authority Required procedures
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			<p>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.</p> <p>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.</p>	
	C11807	P11807	<p>Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of 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</p>	Compliance with Written Authority Required procedures

			<p>the initial application:  an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either  (a) a total active joint count of at least 20 active (swollen and tender) joints; or  (b) at least 4 active joints from the following list of major joints:  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.  If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.  The authority application must be made in writing and must include:  (1) a completed authority prescription form(s); and  (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.  It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.  To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.  Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
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(c) omit:

	C14185	P14185	<p>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</p>	Compliance with Written Authority Required procedures
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			<p>Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>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.</p> <p>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;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>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.</p>	
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(d) insert in numerical order after existing text:

	C14483	P14483	<p>Severe active rheumatoid 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 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/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 at least 18 years of age. Patients who have received PBS-subsidised 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. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. 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 is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a 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</p>	Compliance with Written Authority Required procedures
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			<p>with the initial application, the same marker must be used to determine response.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>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.</p> <p>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.</p>	
	C14486	P14486	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>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).</p> <p>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>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</p>	Compliance with Written Authority Required procedures

			<p>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.</p> <p>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.</p> <p>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.</p>	
	C14488	P14488	<p>Severe active rheumatoid arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p>	Compliance with Authority Required procedures
	C14493	P14493	<p>Severe active rheumatoid arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. 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). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be</p>	Compliance with Written Authority Required procedures

			<p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>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.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>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.</p>	
	C14498	P14498	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>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 at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>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/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>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 contraindicated according to the relevant TGA-approved Product Information/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</p> <p>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</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg</p>	Compliance with Written Authority Required procedures

			<p>weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>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, however the time on treatment must be at least 6 months.</p> <p>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 including severity and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>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 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>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.</p> <p>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.</p>	
	C14499	P14499	<p>Severe active rheumatoid arthritis</p> <p>Subsequent continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority</p>

			<p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR  Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment under this restriction.  Patient must be at least 18 years of age.  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).  The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.  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.  If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	Code 14499
	C14507	P14507	<p>Severe active rheumatoid arthritis  First 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 first continuing treatment restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment.</p>	Compliance with Authority Required procedures

**[259] Schedule 4, Part 1, after entry for Trastuzumab**

*insert:*

Trastuzumab deruxtecan	C14470		<p>Metastatic (Stage IV) HER2 positive breast cancer  Patient must have evidence of human epidermal growth factor (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) in either the primary tumour/a metastatic lesion - establish this finding once only with the first PBS prescription; AND</p>	Compliance with Authority Required procedures
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				<p>The condition must have progressed following treatment with at least one prior HER2 directed regimen for metastatic breast cancer; OR</p> <p>The condition must have, at the time of treatment initiation with this drug, progressed during/within 6 months following adjuvant treatment with a HER2 directed therapy; AND</p> <p>Patient must have, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND</p> <p>The treatment must not be prescribed where any of the following is present: (i) left ventricular ejection fraction of less than 50%, (ii) symptomatic heart failure; confirm cardiac function testing for the first PBS prescription only.</p> <p>Patient must be undergoing initial treatment with this drug - the following are true: (i) this is the first prescription for this drug, (ii) this prescription seeks no more than 3 repeat prescriptions; OR</p> <p>Patient must be undergoing continuing treatment with drug - the following are true: (i) there has been an absence of further disease progression whilst on active treatment with this drug, (ii) this prescription does not seek to re-treat after disease progression, (iii) this prescription seeks no more than 8 repeat prescriptions.</p> <p>Confirm that the following information is documented/retained in the patient's medical records once only with the first PBS prescription:</p> <ol style="list-style-type: none"> <li>1) Evidence of HER2 gene amplification (evidence obtained in relation to past PBS treatment is acceptable).</li> <li>2) Details of prior HER2 directed drug regimens prescribed for the patient.</li> <li>3) Cardiac function test results (evidence obtained in relation to past PBS treatment is acceptable).</li> </ol>	
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**[260] Schedule 4, Part 1, entry for Upadacitinib**

**(a)** *omit:*

	C8638	P8638		<p>Severe active rheumatoid arthritis</p> <p>Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>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</p> <p>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</p> <p>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</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p>	Compliance with Authority Required procedures
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**(b)** *omit:*

	C10340	P10340		<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p>	Compliance with Written Authority Required procedures
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			<p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND  Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND  Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND  The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND  Patient must not receive more than 16 weeks of treatment under this restriction.  Patient must be aged 18 years or older.  Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  All measures of joint count, ESR and/or CRP must be no more than 4 weeks old at the time of application.  If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response 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.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
	C10356	P10356	<p>Severe active rheumatoid arthritis  Continuing treatment  Must be treated by a rheumatologist; OR  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND</p>	Compliance with Written Authority Required procedures



			<p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.  Patient must be aged 18 years or older.  An adequate response to treatment is defined as:  an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;  AND either of the following:  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response 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.  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 has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
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(c) omit:

	C11488	P11488	<p>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 of treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.  Patient must be aged 18 years or older.</p>	Compliance with Authority Required procedures
	C11813	P11813	<p>Severe active rheumatoid arthritis</p>	Compliance with Written

			<p>Initial treatment - Initial 1 (new patient)          Must be treated by a rheumatologist; OR          Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.          Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND          Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR          Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR          Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR          Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND          Patient must not receive more than 16 weeks of treatment under this restriction.          Patient must be aged 18 years or older.          The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.          The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.          If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of 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 to DMARD treatment 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 and/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.</p>	<p>Authority Required procedures</p>
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			<p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response 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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>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.</p> <p>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.</p>	
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(d) omit:

	C14170	P14170	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR</p> <p>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</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>Patients who have received PBS-subsidised 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.</p> <p>An adequate response to treatment is defined as:</p> <p>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;</p> <p>AND either of the following:</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20</p>	Compliance with Written Authority Required procedures
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			<p>active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, conducted within the timeframes specified below.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>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.</p>	
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**(e)** *insert in numerical order after existing text:*

	C14483	P14483	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR</p> <p>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</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p>	Compliance with Written Authority Required procedures
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			<p>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.</p> <p>Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p> <p>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).</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsided biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>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.</p> <p>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.</p> <p>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).</p> <p>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-subsided treatment with this drug for this condition.</p> <p>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsided biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.</p>	
	C14486	P14486	<p>Severe active rheumatoid 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.</p>	Compliance with Written Authority Required procedures

			<p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND  Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND  Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND  The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND  Patient must not receive more than 16 weeks of treatment under this restriction.  Patient must be at least 18 years of age.  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 4 weeks old at the time of initial application.  If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response 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; 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).  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
	C14488	P14488	<p>Severe active rheumatoid arthritis  Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply  Must be treated by a rheumatologist; OR  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p>	Compliance with Authority Required procedures

			<p>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</p> <p>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</p> <p>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</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p>	
	C14498	P14498	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>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 at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>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/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>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 contraindicated according to the relevant TGA-approved Product Information/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</p> <p>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</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>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, however the time on treatment must be at least 6 months.</p> <p>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 including severity and dose for each DMARD must be provided</p>	Compliance with Written Authority Required procedures

			<p>in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>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 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>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.</p> <p>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.</p>	
	C14613	P14613	<p>Severe active rheumatoid arthritis</p> <p>Continuing treatment - balance of supply</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; AND</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment.</p>	Compliance with Authority Required procedures
	C14633	P14633	<p>Severe active rheumatoid arthritis</p> <p>Continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this</p>	Compliance with Written Authority Required procedures



			<p>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 at least 18 years of age.  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).  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; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within 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 has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
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**[261] Schedule 4, Part 1, entry for Ustekinumab**

(a) *omit.*

	C12294	P12294	<p>Severe chronic plaque psoriasis  Initial 2 treatment (Face, hand, foot) - Change or recommencement of treatment after a break in biological medicine of less than 5 years  Must be treated by a dermatologist.  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 more than once</p>	Compliance with Written Authority Required procedures
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			<p>during the current treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND  The treatment must be as systemic monotherapy; OR  The treatment must be in combination with methotrexate; AND  Patient must not receive more than 28 weeks of treatment under this restriction.  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).  Response to preceding supply:  An adequate response to treatment is defined as:  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  Change in therapy:  If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:  (i) there is an absence of an adequate response to that treatment; or  (ii) there was an intolerance to that treatment; or  (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above  Recommencing therapy:  If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:  (i) an absence of an adequate response; or  (ii) an intolerance to that treatment; or  (iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.</p>	
	C12302	P12302	<p>Severe chronic plaque psoriasis  Continuing treatment (Face, hand, foot) - treatment covering week 28 and onwards  Must be treated by a dermatologist.  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  The treatment must be as systemic monotherapy; OR  The treatment must be in combination with methotrexate; AND  Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine; AND  Patient must have demonstrated an adequate response to treatment; AND  Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.  The authority application must be made in writing and must include:  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:</p>	Compliance with Written Authority Required procedures

			(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.	
	C12311	P12311	<p>Severe chronic plaque psoriasis Continuing treatment (Whole body) - treatment covering week 28 and onwards Must be treated by a dermatologist. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate; AND Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine; AND Patient must have demonstrated an adequate response to treatment; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.</p>	Compliance with Written Authority Required procedures
	C12323	P12323	<p>Severe chronic plaque psoriasis Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years Must be treated by a dermatologist. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle; AND The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; OR The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot'; AND Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; OR The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate; AND Patient must not receive more than 28 weeks of treatment under this restriction.</p>	Compliance with Written Authority Required procedures

			<p>Patient must be under 18 years of age.  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  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).</p>	
	C12332	P12332	<p>Severe chronic plaque psoriasis  Initial 2 treatment (Whole body) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years  Must be treated by a dermatologist.  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 more than once during the current treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND  The treatment must be as systemic monotherapy; OR  The treatment must be in combination with methotrexate; AND  Patient must not receive more than 28 weeks of treatment under this restriction.  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).  Response to preceding supply:  An adequate response to treatment is defined as:  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  Change in therapy:  If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:  (i) there is an absence of an adequate response to that treatment; or  (ii) there was an intolerance to that treatment; or  (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above  Recommencing therapy:  If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:  (i) an absence of an adequate response; or  (ii) an intolerance to that treatment; or  (iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.</p>	Compliance with Written Authority Required procedures
	C12333	P12333	<p>Severe chronic plaque psoriasis  Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient</p>	Compliance with Written Authority Required

			<p>Must be treated by a dermatologist.</p> <p>Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; AND</p> <p>The treatment must be as systemic monotherapy; OR</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND</p> <p>Patient must not receive more than 28 weeks of treatment under this restriction.</p> <p>Patient must be under 18 years of age.</p> <p>Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:</p> <p>(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or</p> <p>(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy</p> <p>State in this authority application, each of:</p> <p>(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;</p> <p>(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);</p> <p>(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;</p> <p>(iv) the dates that response assessments were determined</p> <p>State in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:</p> <p>(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);</p> <p>(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.</p>	procedures
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**(b)** omit:

	C12341	P12341	Severe chronic plaque psoriasis Initial 1 treatment (Whole body) - biological medicine-naive patient	Compliance with Written Authority Required
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			<p>Must be treated by a dermatologist.</p> <p>Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; AND</p> <p>The treatment must be as systemic monotherapy; OR</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must have lesions present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND</p> <p>Patient must not receive more than 28 weeks of treatment under this restriction.</p> <p>Patient must be under 18 years of age.</p> <p>Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:</p> <p>(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.</p> <p>A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. State in this authority application, each of:</p> <p>(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;</p> <p>(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);</p> <p>(iii) the PASI score that followed each prior therapy trialled;</p> <p>(iv) the date the PASI scores were determined</p> <p>State a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.</p>	procedures
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**(c)** insert in numerical order after existing text:

	C14543	P14543	<p>Severe chronic plaque psoriasis</p> <p>Initial 1 treatment (Whole body) - biological medicine-naive patient</p> <p>Must be treated by a dermatologist.</p> <p>Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; AND</p> <p>The treatment must be as systemic monotherapy; OR</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must have lesions present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or</p>	Compliance with Written Authority Required procedures
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			<p>PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND</p> <p>Patient must not receive more than 28 weeks of treatment under this restriction.</p> <p>Patient must be under 18 years of age.</p> <p>Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:</p> <p>(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.</p> <p>A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of:</p> <p>(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;</p> <p>(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);</p> <p>(iii) the PASI score that followed each prior therapy trialled;</p> <p>(iv) the date the PASI scores were determined.</p> <p>Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.</p>	
	C14558	P14558	<p>Severe chronic plaque psoriasis</p> <p>Continuing treatment (Whole body) - treatment covering week 28 and onwards</p> <p>Must be treated by a dermatologist.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>The treatment must be as systemic monotherapy; OR</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine; AND</p> <p>Patient must have demonstrated an adequate response to treatment; AND</p> <p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>An adequate response to treatment is defined as:</p>	Compliance with Written Authority Required procedures

			<p>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.</p> <p>The assessment of response to treatment must be provided in this application and documented in the patient's medical records.</p> <p>The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.</p>	
	C14572	P14572	<p>Severe chronic plaque psoriasis</p> <p>Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years</p> <p>Must be treated by a dermatologist.</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle; AND</p> <p>The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; OR</p> <p>The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot'; AND</p> <p>Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; OR</p> <p>The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND</p> <p>The treatment must be as systemic monotherapy; OR</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must not receive more than 28 weeks of treatment under this restriction.</p> <p>Patient must be under 18 years of age.</p> <p>The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p>	Compliance with Written Authority Required procedures
	C14573	P14573	<p>Severe chronic plaque psoriasis</p> <p>Initial 2 treatment (Face, hand, foot) - Change or recommencement of treatment after a break in biological medicine of less than 5 years</p> <p>Must be treated by a dermatologist.</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>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</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND</p> <p>The treatment must be as systemic monotherapy; OR</p>	Compliance with Written Authority Required procedures



			<p>The treatment must be in combination with methotrexate; AND  Patient must not receive more than 28 weeks of treatment under this restriction.  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).  Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.  Response to preceding supply:  An adequate response to treatment is defined as:  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  Change in therapy:  If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:  (i) there is an absence of an adequate response to that treatment; or  (ii) there was an intolerance to that treatment; or  (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above  Recommencing therapy:  If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:  (i) an absence of an adequate response; or  (ii) an intolerance to that treatment; or  (iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.  The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.</p>	
	C14628	P14628	<p>Severe chronic plaque psoriasis  Continuing treatment (Face, hand, foot) - treatment covering week 28 and onwards  Must be treated by a dermatologist.  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  The treatment must be as systemic monotherapy; OR  The treatment must be in combination with methotrexate; AND  Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine; AND  Patient must have demonstrated an adequate response to treatment; AND  Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.  The authority application must be made in writing and must include:  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:</p>	Compliance with Written Authority Required procedures

			<p>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or</p> <p>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.</p> <p>The assessment of response to treatment must be provided in this application and documented in the patient's medical records.</p>	
	C14636	P14636	<p>Severe chronic plaque psoriasis</p> <p>Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient</p> <p>Must be treated by a dermatologist.</p> <p>Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; AND</p> <p>The treatment must be as systemic monotherapy; OR</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND</p> <p>Patient must not receive more than 28 weeks of treatment under this restriction.</p> <p>Patient must be under 18 years of age.</p> <p>Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:</p> <p>(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or</p> <p>(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy</p> <p>Provide in this authority application, and document in the patient's medical records, each of:</p> <p>(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;</p> <p>(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);</p> <p>(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;</p> <p>(iv) the dates that response assessments were determined.</p> <p>Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:</p>	Compliance with Written Authority Required procedures

				(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe); (vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.	
	C14643	P14643		<p>Severe chronic plaque psoriasis Initial 2 treatment (Whole body) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years Must be treated by a dermatologist. 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 more than once during the current treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate; AND Patient must not receive more than 28 weeks of treatment under this restriction. 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). Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application. Response to preceding supply: An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. Change in therapy: If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because: (i) there is an absence of an adequate response to that treatment; or (ii) there was an intolerance to that treatment; or (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above Recommencing therapy: If the patient is recommencing therapy, in relation to the last administered dose, state whether there was: (i) an absence of an adequate response; or (ii) an intolerance to that treatment; or (iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above. The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.</p>	Compliance with Written Authority Required procedures

**[262] Schedule 5, after entry for Amoxicillin with clavulanic acid in the form Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (s19A)**

*insert:*

	GRP-28006	Powder for oral suspension containing 400 mg amoxicillin (as trihydrate) with 57 mg clavulanic acid (as potassium clavulanate) per 5 mL, 50 mL (S19A)	Oral	Amoxicillin and clavulanate potassium for oral suspension, USP 400 mg/57 mg per 5 mL (Aurobindo)
		Powder for oral suspension containing 400 mg amoxicillin (as trihydrate) with 57 mg clavulanic acid (as potassium clavulanate) per 5 mL, 60 mL	Oral	Augmentin Duo 400 Curam Duo

**[263] Schedule 5, after entry for Methylprednisolone in the form Powder for injection 40 mg (as sodium succinate) with diluent**

*insert:*

		Powder for injection 40 mg (as sodium succinate) (S19A)	Injection	Solu-Medrone
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**[264] Schedule 5, entry for Varenicline in the form Tablet 1 mg (as tartrate)**

*insert in alphabetical order in the column headed "Brand":* **PHARMACOR VARENICLINE**