

**PB 43 of 2023**

**National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023  
(No. 5)**

*National Health Act 1953*

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

Dated 30 May 2023

**NIKOLAI TSYGANOV**

Assistant Secretary

Pricing and PBS Policy Branch

Technology Assessment and Access Division

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National Health (Listing of Pharmaceutical Benefits) Instrument 2012   
(PB 71 of 2012). 2

1 Name

1. This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 5)*.
2. This Instrument may also be cited as PB 43 of 2023.

2 Commencement

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

| Commencement information | | |
| --- | --- | --- |
| Column 1 | Column 2 | Column 3 |
| Provisions | Commencement | Date/Details |
| 1. *The whole of this instrument* | *1 June 2023* | *1 June 2023* |

Note: This table relates only to the provisions of this instrument as originally made.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

1. 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Ambrisentan in the form Tablet 5 mg
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Ambrisentan Viatris | AL | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 30 |  | D(100) |

1. Schedule 1, Part 1, entry for Amisulpride in the form Tablet 200 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Amisulpride 200 Winthrop | WA | MP NP | C4246 |  | 60 | 5 | 60 |  |  |

1. Schedule 1, Part 1, entry for Amlodipine in each of the forms: Tablet 5 mg (as besilate); and Tablet 10 mg (as besilate)
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Blooms Amlodipine | BG | MP NP |  |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, 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)
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (s19A) | Oral |  | Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Medsurge) | DZ | MP NP | C5832 C5893 C10413 | P5832 P5893 | 10 | 0 | 20 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 20 |  |  |
|  |  |  |  | Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals) | QY | MP NP | C5832 C5893 C10413 | P5832 P5893 | 10 | 0 | 20 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 20 |  |  |
|  |  |  |  | Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs) | QZ | MP NP | C5832 C5893 C10413 | P5832 P5893 | 10 | 0 | 20 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 20 |  |  |
|  |  |  |  | Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Medsurge) | DZ | MP NP | C5832 C5893 C10413 | P10413 | 20 | 0 | 20 |  |  |
|  |  |  |  | Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals) | QY | MP NP | C5832 C5893 C10413 | P10413 | 20 | 0 | 20 |  |  |
|  |  |  |  | Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs) | QZ | MP NP | C5832 C5893 C10413 | P10413 | 20 | 0 | 20 |  |  |

1. Schedule 1, Part 1, entry for Apalutamide
   1. *insert in numerical order in the column headed “Circumstances”:* C14034
2. Schedule 1, Part 1, entry for Azacitidine
   * 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | AZACITIDINE DR.REDDY'S | RI | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 1 |  | D(100) |

* + 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Azadine | RZ | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 1 |  | D(100) |

1. Schedule 1, Part 1, entry for Baricitinib in the form Tablet 2 mg *[Maximum Quantity: 28; Number of Repeats: 5]*
   1. *omit from the column headed “Pack Quantity”:* **3**  *substitute:* **28**
2. Schedule 1, Part 1, entry for Bimatoprost in the form Eye drops 300 micrograms per mL, single dose units 0.4 mL, 30
   1. *omit from the column headed “Responsible Person”:* AG *substitute:* VE
3. Schedule 1, Part 1, entry for Bimatoprost in the form Eye drops 300 micrograms per mL, 3 mL
   1. *omit from the column headed “Responsible Person” for the brand “Lumigan”:* AG *substitute:* VE
4. Schedule 1, Part 1, entry for Bimatoprost with timolol in each of the forms: Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, single dose units 0.4 mL, 30; and Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, 3 mL
   1. *omit from the column headed “Responsible Person”:* AG *substitute:* VE
5. Schedule 1, Part 1, entry for Bortezomib in the form Powder for injection 3.5 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Bortezomib-Dr.Reddy's | RI | MP | C11099 C13745 |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. Schedule 1, Part 1, entry for Botulinum toxin type A purified neurotoxin complex
   1. *omit from the column headed “Responsible Person”:* AG *substitute:* VE
2. Schedule 1, Part 1, entry for Brimonidine in the form Eye drops containing brimonidine tartrate 1.5 mg per mL, 5 mL
   1. *omit from the column headed “Responsible Person”:* AG *substitute:* VE
3. Schedule 1, Part 1, entry for Brimonidine in the form Eye drops containing brimonidine tartrate 2 mg per mL, 5 mL
   * 1. *omit from the column headed “Responsible Person” for the brand “Alphagan”:* AG *substitute:* VE
     2. *omit from the column headed “Responsible Person” for the brand “Enidin”:* PE *substitute:* VB
4. Schedule 1, Part 1, entry for Brimonidine with timolol
   1. *omit from the column headed “Responsible Person”:* AG *substitute:* VE
5. Schedule 1, Part 1, entry for Cannabidiol
   1. *insert in numerical order in the column headed “Circumstances”:* C14047
6. Schedule 1, Part 1, entry for Carmellose
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Carmellose | Eye drops containing carmellose sodium 5 mg per mL, single dose units 0.4 mL, 30 | Application to the eye | a | Cellufresh | VE | MP NP AO | C6172 |  | 3 | 5 | 1 |  |  |
|  |  |  | a | Optifresh Tears | PP | MP NP AO | C6172 |  | 3 | 5 | 1 |  |  |
|  | Eye drops containing carmellose sodium 5 mg per mL, 10 mL | Application to the eye |  | Evolve Carmellose | CX | MP NP AO | C6172 |  | 1 | 5 | 1 |  |  |
|  | Eye drops containing carmellose sodium 5 mg per mL, 15 mL | Application to the eye |  | Refresh Tears Plus | VE | AO | C6120 |  | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C6073 C6098 | P6073 | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | NP | C6073 |  | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C6073 C6098 | P6098 | 1 | 11 | 1 |  |  |
|  | Eye drops containing carmellose sodium 10 mg per mL, single dose units 0.4 mL, 30 | Application to the eye | a | Celluvisc | VE | MP NP AO | C6172 |  | 3 | 5 | 1 |  |  |
|  |  |  | a | Optifresh Plus | PP | MP NP AO | C6172 |  | 3 | 5 | 1 |  |  |
|  | Eye drops containing carmellose sodium 10 mg per mL, 15 mL | Application to the eye |  | Refresh Liquigel | VE | AO | C6120 |  | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C6073 C6098 | P6073 | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | NP | C6073 |  | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C6073 C6098 | P6098 | 1 | 11 | 1 |  |  |

1. Schedule 1, Part 1, entry for Carmellose with glycerin
   1. *omit from the column headed “Responsible Person”:* AG *substitute:* VE
2. Schedule 1, Part 1, entry for Cefalexin in the form Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL
   1. *omit from the column headed “Schedule Equivalent” (all instances):* a
3. Schedule 1, Part 1, after entry for Cefalexin in the form Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL *[Maximum Quantity: 1; Number of Repeats: 1]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL (s19A) | Oral |  | Keforal | QY | PDP |  |  | 1 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP NP |  |  | 1 | 1 | 1 |  |  |

1. Schedule 1, Part 1, entry for Ceftriaxone in the form Powder for injection 1 g (as sodium)
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Ceftriaxone Viatris | AL | MP NP | C5830 C5862 C5868 |  | 5 | 0 | 5 |  |  |
|  |  |  |  |  |  | MP NP | C5830 C5862 C5868 |  | 5 | 0 | 10 |  |  |

1. Schedule 1, Part 1, entry for Ceftriaxone in the form Powder for injection 2 g (as sodium)
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Ceftriaxone Viatris | AL | MP NP | C5826 C5881 C5890 |  | 5 | 0 | 5 |  |  |
|  |  |  |  |  |  | MP NP | C5826 C5881 C5890 |  | 5 | 0 | 10 |  |  |

1. Schedule 1, Part 1, after entry for Ciclosporin in the form Capsule 100 mg *[Maximum Quantity: 120; Number of Repeats: 5]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Eye drops 900 micrograms per mL, single dose units 0.25 mL, 60 | Application to the eye |  | Cequa | RA | MP AO | C14026 C14032 |  | 1 | 5 | 1 |  |  |

1. Schedule 1, Part 1, entry for Ciclosporin in the form Eye drops 1 mg per mL, single dose units 0.3 mL, 30
   1. *omit from the column headed “Circumstances”:* C12284 C12346 *substitute:* C14026 C14032
2. Schedule 1, Part 1, entry for Ciprofloxacin in the form Tablet 500 mg (as hydrochloride)
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Ciprofloxacin GH | HQ | MP NP | C5614 C5615 C5687 C5688 C5689 C5722 C5780 |  | 14 | 0 | 14 |  |  |

1. Schedule 1, Part 1, entry for Dexamethasone in the form Intravitreal injection 700 micrograms
   1. *omit from the column headed “Responsible Person”:* AG *substitute:* VE
2. Schedule 1, Part 1, after entry for Disopyramide in the form Capsule 100 mg
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Capsule 100 mg (s19A) | Oral |  | Rythmodan (Canada) | OJ | MP NP |  |  | 100 | 5 | 84 |  |  |

1. Schedule 1, Part 1, entry for Donepezil in each of the forms: Tablet containing donepezil hydrochloride 5 mg; and Tablet containing donepezil hydrochloride 10 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Donepezil-DRLA | RZ | MP | C13938 C13940 C13941 |  | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C13938 |  | 28 | 5 | 28 |  |  |

1. Schedule 1, Part 1, entry for Dosulepin in the form Capsule containing dosulepin hydrochloride 25 mg
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Dosulepin Viatris | MQ | MP NP |  |  | 50 | 2 | 50 |  |  |

1. Schedule 1, Part 1, entry for Escitalopram in each of the forms: Tablet 10 mg (as oxalate); and Tablet 20 mg (as oxalate)
   1. *omit from the column headed “Circumstances”:* C4755 *substitute:* C4690 C4703 C4755 C4756 C4757
2. Schedule 1, Part 1, entry for Ezetimibe
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | BTC Ezetimibe | BG | MP NP | C7966 C7990 C7996 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 2.063 mg
   1. *omit from the column headed “Responsible Person”:* ZP *substitute:* RW
2. Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 4.125 mg
   1. *omit from the column headed “Responsible Person”:* ZP *substitute:* RW
3. Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 8.25 mg
   1. *omit from the column headed “Responsible Person”:* ZP *substitute:* RW
4. Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 12.375 mg
   1. *omit from the column headed “Responsible Person”:* ZP *substitute:* RW
5. Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 16.5 mg
   1. *omit from the column headed “Responsible Person”:* ZP *substitute:* RW
6. Schedule 1, Part 1, entry for Fingolimod in the form Capsule 500 micrograms (as hydrochloride)
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Fingolimod-Teva | TB | MP | C10162 C10172 |  | 28 | 5 | 28 |  |  |

1. Schedule 1, Part 1, entry for Fluorometholone in the form Eye drops 1 mg per mL, 5 mL
   1. *omit from the column headed “Responsible Person”:* AG *substitute:* VE
2. Schedule 1, Part 1, entry for Fluticasone propionate with salmeterol in the form Powder for oral inhalation in breath actuated device containing fluticasone propionate 500 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Fluticasone Salmeterol Ciphaler 500/50 | LR | MP NP | C4930 C10121 |  | 1 | 5 | 1 |  |  |

1. Schedule 1, Part 1, entry for Fosaprepitant
   * 1. *insert in the column headed “Schedule Equivalent” for the brand “Emend IV”:* **a**
     2. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | FOSAPREPITANT-AFT | AE | MP NP | C6852 C6886 C6887 C6891 |  | 1 | 5 | 1 |  |  |

1. Schedule 1, Part 1, entry for Gentamicin in the form Eye drops 3 mg (as sulfate) per mL, 5 mL
   1. *omit from the column headed “Responsible Person”:* AG *substitute:* VE
2. Schedule 1, Part 1, entry for Gliclazide in the form Tablet 60 mg (modified release)
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Gliclazide Lupin MR | GQ | MP NP |  |  | 60 | 5 | 60 |  |  |

1. Schedule 1, Part 1, entry for Labetalol
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing labetalol hydrochloride 200 mg | Oral | a | Trandate | AS | MP NP |  |  | 100 | 5 | 100 |  |  |

1. Schedule 1, Part 1, after entry for Larotrectinib in the form Capsule 100 mg (as sulfate) *[Maximum Quantity: 56; Number of Repeats: 5]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Oral solution 20 mg per mL (as sulfate), 50 mL, 2 | Oral |  | VITRAKVI | BN | MP | C12980 C12981 C12982 | P12981 P12982 | 1 | 2 | 1 |  |  |
|  |  |  |  |  |  | MP | C12980 C12981 C12982 | P12980 | 1 | 5 | 1 |  |  |

1. Schedule 1, Part 1, entry for Leflunomide in the form Tablet 10 mg
   1. *omit from the column headed “Responsible Person” for the brand “Lunava 10”:* ZP *substitute:* RW
2. Schedule 1, Part 1, entry for Leflunomide in the form Tablet 20 mg
   1. *omit from the column headed “Responsible Person” for the brand “Lunava 20”:* ZP *substitute:* RW
3. Schedule 1, Part 1, entry for Lenalidomide
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lenalidomide | Capsule 5 mg | Oral |  | Cipla Lenalidomide | LR | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 28 |  | D(100) |
|  |  |  |  | Lenalide | JU | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 28 |  | D(100) |
|  |  |  |  | Lenalidomide Dr.Reddy's | RI | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 28 |  | D(100) |
|  |  |  |  | Lenalidomide Sandoz | SZ | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 28 |  | D(100) |
|  |  |  |  | Lenalidomide-Teva | TB | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 28 |  | D(100) |
|  |  |  |  | Lenalidomide Viatris | AF | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  | Revlimid | CJ | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 28 |  | D(100) |
|  | Capsule 10 mg | Oral |  | Cipla Lenalidomide | LR | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 28 |  | D(100) |
|  |  |  |  | Lenalide | JU | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 28 |  | D(100) |
|  |  |  |  | Lenalidomide Dr.Reddy's | RI | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 28 |  | D(100) |
|  |  |  |  | Lenalidomide Sandoz | SZ | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 28 |  | D(100) |
|  |  |  |  | Lenalidomide-Teva | TB | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 28 |  | D(100) |
|  |  |  |  | Lenalidomide Viatris | AF | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  | Revlimid | CJ | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 28 |  | D(100) |
|  | Capsule 15 mg | Oral |  | Cipla Lenalidomide | LR | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 28 |  | D(100) |
|  |  |  |  | Lenalide | JU | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 28 |  | D(100) |
|  |  |  |  | Lenalidomide Dr.Reddy's | RI | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 28 |  | D(100) |
|  |  |  |  | Lenalidomide Sandoz | SZ | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 28 |  | D(100) |
|  |  |  |  | Lenalidomide-Teva | TB | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 28 |  | D(100) |
|  |  |  |  | Lenalidomide Viatris | AF | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  | Revlimid | CJ | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 28 |  | D(100) |
|  | Capsule 25 mg | Oral |  | Cipla Lenalidomide | LR | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  | Lenalide | JU | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  | Lenalidomide Dr.Reddy's | RI | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  | Lenalidomide Sandoz | SZ | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  | Lenalidomide-Teva | TB | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  | Lenalidomide Viatris | AF | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |
|  |  |  |  | Revlimid | CJ | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 14 |  | D(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 21 |  | D(100) |

1. Schedule 1, Part 1, entry for Lenvatinib in the form Capsule 4 mg (as mesilate) *[Maximum Quantity: 30; Number of Repeats: 2]*
   1. *insert in numerical order in the column headed “Circumstances”:* C14041 C14042 C14043
2. Schedule 1, Part 1, entry for Lenvatinib in the form Capsule 4 mg (as mesilate) *[Maximum Quantity: 60; Number of Repeats: 2]*
   * 1. *insert in numerical order in the column headed “Circumstances”:* C14041 C14042 C14043
     2. *insert in numerical order in the column headed “Purposes”:* P14041 P14042 P14043
3. Schedule 1, Part 1, entry for Lenvatinib in the form Capsule 4 mg (as mesilate) *[Maximum Quantity: 90; Number of Repeats: 2]*
   1. *insert in numerical order in the column headed “Circumstances”:* C14041 C14042 C14043
4. Schedule 1, Part 1, entry for Lenvatinib in the form Capsule 10 mg (as mesilate)
   1. *insert in numerical order in the column headed “Circumstances”:* C14041 C14042 C14043
5. Schedule 1, Part 1, entry for Levonorgestrel with ethinylestradiol in the form Pack containing 6 tablets 50 micrograms-30 micrograms, 5 tablets 75 micrograms-40 micrograms, 10 tablets 125 micrograms-30 micrograms and 7 inert tablets
   * 1. *omit from the column headed “Schedule Equivalent” for the brand “Logynon ED”:* **b** *substitute:* **a**
     2. *omit from the column headed “Schedule Equivalent” for the brand “Trifeme 28”:* **a**
     3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Triphasil 28 | PF | MP NP |  |  | 4 | 2 | 4 |  |  |

* + 1. *omit from the column headed “Schedule Equivalent” for the brand “Triquilar ED”:* **b** *substitute:* **a**

1. Schedule 1, Part 1, entry for Levothyroxine
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Levothyroxine | Tablet containing 50 micrograms anhydrous levothyroxine sodium | Oral | b | Eltroxin | LT | MP NP |  |  | 200 | 1 | 200 |  |  |
|  |  |  | a | Eutroxsig | LN | MP NP |  |  | 200 | 1 | 200 |  |  |
|  |  |  | b | Levothox | AF | MP NP |  |  | 200 | 1 | 200 |  |  |
|  |  |  | a | LEVOXINE | RA | MP NP |  |  | 200 | 1 | 200 |  |  |
|  |  |  | a | Oroxine | AS | MP NP |  |  | 200 | 1 | 200 |  |  |
|  | Tablet containing 75 micrograms anhydrous levothyroxine sodium | Oral | b | Eltroxin | LT | MP NP |  |  | 200 | 1 | 200 |  |  |
|  |  |  | a | Eutroxsig | LN | MP NP |  |  | 200 | 1 | 200 |  |  |
|  |  |  | b | Levothox | AF | MP NP |  |  | 200 | 1 | 200 |  |  |
|  |  |  | a | LEVOXINE | RA | MP NP |  |  | 200 | 1 | 200 |  |  |
|  |  |  | a | Oroxine | AS | MP NP |  |  | 200 | 1 | 200 |  |  |
|  | Tablet containing 100 micrograms anhydrous levothyroxine sodium | Oral | b | Eltroxin | LT | MP NP |  |  | 200 | 1 | 200 |  |  |
|  |  |  | a | Eutroxsig | LN | MP NP |  |  | 200 | 1 | 200 |  |  |
|  |  |  | b | Levothox | AF | MP NP |  |  | 200 | 1 | 200 |  |  |
|  |  |  | a | LEVOXINE | RA | MP NP |  |  | 200 | 1 | 200 |  |  |
|  |  |  | a | Oroxine | AS | MP NP |  |  | 200 | 1 | 200 |  |  |
|  | Tablet containing 125 micrograms anhydrous levothyroxine sodium | Oral | a | Eltroxin | LT | MP NP |  |  | 200 | 1 | 200 |  |  |
|  |  |  | a | Levothox | AF | MP NP |  |  | 200 | 1 | 200 |  |  |
|  | Tablet containing 200 micrograms anhydrous levothyroxine sodium | Oral | b | Eltroxin | LT | MP NP |  |  | 200 | 1 | 200 |  |  |
|  |  |  | a | Eutroxsig | LN | MP NP |  |  | 200 | 1 | 200 |  |  |
|  |  |  | b | Levothox | AF | MP NP |  |  | 200 | 1 | 200 |  |  |
|  |  |  | a | LEVOXINE | RA | MP NP |  |  | 200 | 1 | 200 |  |  |
|  |  |  | a | Oroxine | AS | MP NP |  |  | 200 | 1 | 200 |  |  |

1. Schedule 1, Part 1, entry for Lisinopril in each of the forms: Tablet 5 mg; and Tablet 10 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Lisinopril generichealth | GQ | MP NP |  |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, after entry for Minoxidil in the form Tablet 10 mg
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 10 mg (s19A) | Oral |  | Minoxidil 10 mg (Roma Pharmaceuticals) | OJ | MP NP | C5177 |  | 100 | 5 | 60 |  |  |

1. Schedule 1, Part 1, entry for Mometasone in the form Lotion containing mometasone furoate 1 mg per g, 30 mL
   * 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Momasone | AS | MP NP | C4957 C6218 C6231 C6232 C6246 C6263 | P4957 | 1 | 0 | 1 |  |  |

* + 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Momasone | AS | MP NP | C4957 C6218 C6231 C6232 C6246 C6263 | P6232 | 2 | 5 | 1 |  |  |

* + 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Momasone | AS | MP NP | C4957 C6218 C6231 C6232 C6246 C6263 | P6246 | 3 | 5 | 1 |  |  |

* + 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Momasone | AS | MP NP | C4957 C6218 C6231 C6232 C6246 C6263 | P6218 P6263 | 4 | 5 | 1 |  |  |

* + 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Momasone | AS | MP NP | C4957 C6218 C6231 C6232 C6246 C6263 | P6231 | 5 | 5 | 1 |  |  |

1. Schedule 1, Part 1, entry for Naltrexone
   1. *omit from the column headed “Authorised Prescriber”:* MP *substitute:* MP NP
2. Schedule 1, Part 1, entry for Nicotine
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Nicotine | Transdermal patch 17.5 mg | Transdermal |  | Nicotinell Step 3 | ON | MP NP | C14040 |  | 28 | 2 | 28 |  |  |
|  | Transdermal patch 35 mg | Transdermal |  | Nicotinell Step 2 | ON | MP NP | C14040 |  | 28 | 2 | 28 |  |  |
|  | Transdermal patch 39.4 mg | Transdermal |  | nicorette 16hr Invisipatch | JT | MP NP | C14040 |  | 28 | 2 | 28 |  |  |
|  | Transdermal patch 52.5 mg | Transdermal |  | Nicotinell Step 1 | ON | MP NP | C5140 C14040 |  | 28 | 2 | 28 |  |  |
|  | Transdermal patch 114 mg | Transdermal |  | Nicabate P | GJ | MP NP | C14040 |  | 28 | 2 | 28 |  |  |

1. Schedule 1, Part 1, entry for Ofloxacin
   1. *omit from the column headed “Responsible Person”:* AG *substitute:* VE
2. Schedule 1, Part 1, entry for Olanzapine in each of the forms: Tablet 2.5 mg; and Tablet 5 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Olanzapine-DRLA | RZ | MP NP | C5856 C5869 |  | 28 | 5 | 28 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Olanzapine-DRLA | RZ | MP NP | C5856 C5869 |  | 28 | 5 | 28 |  |  |

1. Schedule 1, Part 1, entry for Olmesartan in each of the forms: Tablet containing olmesartan medoxomil 20 mg; and Tablet containing olmesartan medoxomil 40 mg
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Olsetan | MQ | MP NP |  |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Omeprazole in the form Tablet 20 mg
   1. *omit from the column headed “Responsible Person” for the brand “Ozmep” (all instances):* ZP *substitute (all instances):* RW
2. Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg
   * 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Ondansetron ODT GH | GQ | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 |  |  |
|  |  |  |  |  |  | MP | C5743 |  | 4 | 0 | 4 |  | C(100) |

* + 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Ondansetron ODT GH | GQ | MP NP | C5618 C10498 | P10498 | 10 | 1 | 10 |  |  |

1. Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg
   * 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Ondansetron ODT GH | GQ | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 |  |  |
|  |  |  |  |  |  | MP | C5743 |  | 4 | 0 | 4 |  | C(100) |

* + 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Ondansetron ODT GH | GQ | MP NP | C5618 C10498 | P10498 | 10 | 1 | 10 |  |  |

1. Schedule 1, Part 1, entry for Paracetamol in the form Tablet 665 mg (modified release) *[Maximum Quantity: 192; Number of Repeats: 3]*
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Parapane OSTEO | AF | MP NP | C6225 C6280 | P6225 | 192 | 3 | 96 |  |  |

1. Schedule 1, Part 1, entry for Paracetamol in the form Tablet 665 mg (modified release) *[Maximum Quantity: 192; Number of Repeats: 5]*
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Parapane OSTEO | AF | MP NP | C6225 C6280 | P6280 | 192 | 5 | 96 |  |  |

1. Schedule 1, Part 1, entry for Paraffin in the form Pack containing 2 tubes eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g
   1. *omit from the column headed “Responsible Person” for the brand “Refresh Night Time” (all instances):* AG *substitute (all instances):* VE
2. Schedule 1, Part 1, entry for Paroxetine
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Blooms The Chemist Paroxetine | BG | MP NP | C4755 C6277 C6636 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Pembrolizumab
   1. *insert in numerical order in the column headed “Circumstances”:* C14027 C14028 C14044
2. Schedule 1, Part 1, after entry for Phenoxymethylpenicillin in the form Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL *[Maximum Quantity: 2; Number of Repeats: 1]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL (s19A) | Oral |  | Penopen | QY | PDP |  |  | 2 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP NP |  |  | 2 | 1 | 1 |  |  |

1. Schedule 1, Part 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 80 mg
   * 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Pravastatin generichealth | GQ | MP NP |  |  | 30 | 5 | 30 |  |  |

* + 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Pravastatin generichealth | GQ | MP |  | P7598 | 30 | 11 | 30 |  |  |

1. Schedule 1, Part 1, entry for Prednisolone with phenylephrine
   1. *omit from the column headed “Responsible Person”:* AG *substitute:* VE
2. Schedule 1, Part 1, entry for Pregabalin in the form Capsule 25 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Pregabalin GH | GQ | MP NP | C4172 |  | 56 | 5 | 56 |  |  |

1. Schedule 1, Part 1, entry for Quinapril in the form Tablet 20 mg (as hydrochloride)
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Quinapril generichealth | GQ | MP NP |  |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Ranitidine in the form Tablet 150 mg (as hydrochloride)
   * 1. *omit from the column headed “Schedule Equivalent” for the brand “APO-Ranitidine”:* **a**
     2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Zantac | AS | MP NP MW |  |  | 60 | 5 | 60 |  |  |

1. Schedule 1, Part 1, entry for Ranitidine in the form Tablet 300 mg (as hydrochloride)
   * 1. *omit from the column headed “Schedule Equivalent” for the brand “APO-Ranitidine”:* **a**
     2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Zantac | AS | MP NP |  |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Rasagiline
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Rasazil | GQ | MP NP | C5339 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Selinexor
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Selinexor | Tablet 20 mg | Oral |  | Xpovio | TG | MP | C13161 C14021 C14022 C14023 C14024 C14031 C14037 C14039 C14045 | P14021 P14022 P14045 | 16 | 2 | 16 |  | D(100) |
|  |  |  |  |  |  | MP | C13161 C14021 C14022 C14023 C14024 C14031 C14037 C14039 C14045 | P14023 P14024 P14037 | 20 | 2 | 20 |  | D(100) |
|  |  |  |  |  |  | MP | C13161 C14021 C14022 C14023 C14024 C14031 C14037 C14039 C14045 | P13161 P14031 P14039 | 32 | 2 | 32 |  | D(100) |

1. Schedule 1, Part 1, entry for Telmisartan in the form Tablet 80 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Telmisartan GH | GQ | MP NP |  |  | 28 | 5 | 28 |  |  |

1. Schedule 1, Part 1, entry for Telmisartan with hydrochlorothiazide in the form Tablet 40 mg-12.5 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Telmisartan HCT GH 40/12.5 | GQ | MP NP | C4374 |  | 28 | 5 | 28 |  |  |

1. Schedule 1, Part 1, entry for Telmisartan with hydrochlorothiazide in the form Tablet 80 mg-12.5 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Telmisartan HCT GH 80/12.5 | GQ | MP NP | C4374 |  | 28 | 5 | 28 |  |  |

1. Schedule 1, Part 1, entry for Tenofovir with emtricitabine in the form Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Tenofovir Disoproxil Emtricitabine Viatris 300/200 | AL | MP NP | C11143 |  | 30 | 2 | 30 |  |  |
|  |  |  |  |  |  | MP NP | C6985 C6986 |  | 60 | 5 | 30 |  | C(100) |

1. Schedule 1, Part 1, entry for Venlafaxine in the form Capsule (modified release) 37.5 mg (as hydrochloride)
   1. *omit from the column headed “Responsible Person” for the brand “Elaxine SR 37.5”:* ZP *substitute:* RW
2. Schedule 1, Part 1, entry for Venlafaxine in the form Capsule (modified release) 75 mg (as hydrochloride)
   1. *omit from the column headed “Responsible Person” for the brand “Elaxine SR 75”:* ZP *substitute:* RW
3. Schedule 1, Part 1, entry for Venlafaxine in the form Capsule (modified release) 150 mg (as hydrochloride)
   1. *omit from the column headed “Responsible Person” for the brand “Elaxine SR 150”:* ZP *substitute:* RW
4. Schedule 1, Part 1, entry for Vinorelbine in the form Capsule 20 mg (as tartrate)
   * 1. *insert in the column headed “Schedule Equivalent” for the brand “Navelbine”:* **a**
     2. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Velabine | LI | MP | C4242 C4272 |  | 20 | 2 | 1 |  |  |

1. Schedule 1, Part 1, entry for Vinorelbine in the form Capsule 30 mg (as tartrate)
   * 1. *insert in the column headed “Schedule Equivalent” for the brand “Navelbine”:* **a**
     2. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Velabine | LI | MP | C4242 C4272 |  | 16 | 2 | 1 |  |  |

1. Schedule 1, Part 2, omit entry for Abatacept
2. Schedule 1, Part 2, omit entry for Adalimumab
3. Schedule 1, Part 2, omit entry for Ampicillin
4. Schedule 1, Part 2, omit entry for Baricitinib
5. Schedule 1, Part 2, omit entry for Certolizumab pegol
6. Schedule 1, Part 2, omit entry for Dipyridamole with aspirin
7. Schedule 1, Part 2, entry for Donepezil in each of the forms: Tablet containing donepezil hydrochloride 5 mg; and Tablet containing donepezil hydrochloride 10 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Donepezil-DRLA | RZ | MP | C10099 C10100 |  | 28 | 5 | 28 |  |  |

1. Schedule 1, Part 2, omit entry for Doxepin
2. Schedule 1, Part 2, omit entry for Etanercept
3. Schedule 1, Part 2, omit entry for Golimumab
4. Schedule 1, Part 2, omit entry for Infliximab
5. Schedule 1, Part 2, after entry for Insulin aspart in the form Injections (human analogue) (fast acting), pre-filled pen, 100 units per mL,   
   3 mL, 5
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Labetalol | Tablet containing labetalol hydrochloride 200 mg | Oral | a | Trandate | AS | MP NP |  |  | 100 | 5 | 100 |  |  |

1. Schedule 1, Part 2, omit entry for Pindolol
2. Schedule 1, Part 2, entry for Polyvinyl alcohol
   * 1. *omit from the column headed “Responsible Person” for the brand “Liquifilm Tears” (all instances):* **AG** *substitute (all instances):* **VE**
     2. *omit* *from the column headed “Responsible Person” for the brand “PVA Tears” (all instances):* **PE** *substitute (all instances):* **VB**
3. Schedule 1, Part 2, omit entry for Risedronic acid and calcium
4. Schedule 1, Part 2, omit entry for Tofacitinib
5. Schedule 1, Part 2, omit entry for Upadacitinib
6. Schedule 3,
   1. *omit:*

|  |  |  |
| --- | --- | --- |
| AG | Allergan Australia Pty Limited | 85 000 612 831 |

1. Schedule 3,
   1. *omit:*

|  |  |  |
| --- | --- | --- |
| PE | Allergan Australia Pty Limited | 85 000 612 831 |

1. Schedule 3, after details relevant to Responsible Person code QY
   1. *insert:*

|  |  |  |
| --- | --- | --- |
| QZ | Pro Pharmaceuticals Group Pty. Ltd. | 20 605 457 430 |

1. Schedule 3, after details relevant to Responsible Person code UR
   1. *insert:*

|  |  |  |
| --- | --- | --- |
| VB | AbbVie Pty Ltd | 48 156 384 262 |

1. Schedule 4, Part 1, entry for Abatacept
   1. *omit:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C12378 | P12378 |  | Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing 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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; 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. 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 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. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |
|  | C12385 | P12385 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; 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 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. 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 authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) 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. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within 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. 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 5 repeats. Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 5 repeats. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Adalimumab
   1. *omit:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C12354 | P12354 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; 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. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) 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. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within 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. | Compliance with Written Authority Required procedures |
|  | C12364 | P12364 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
|  | C12366 | P12366 |  | Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing 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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); 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; 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. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |
|  | C12391 | P12391 |  | Severe active juvenile idiopathic arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing 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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Apalutamide
   1. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14034 |  |  | Metastatic castration sensitive carcinoma of the prostate The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy; AND Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug. Patient must be undergoing concurrent androgen deprivation therapy. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Baricitinib
   1. *omit:*

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| --- | --- | --- | --- | --- | --- |
|  | C12354 | P12354 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; 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. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) 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. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within 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. | Compliance with Written Authority Required procedures |
|  | C12366 | P12366 |  | Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing 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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); 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; 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. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Cannabidiol
   1. *insert in numerical order after existing text:*

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|  | C14047 |  |  | Seizures of the Lennox-Gastaut syndrome Patient must have a diagnosis of Lennox-Gastaut syndrome confirmed by an electroencephalogram (EEG) that showed a pattern of slow (less than 3.0 hertz) spike-and-wave discharges with generalised paroxysmal fast activity (sleep recording should be obtained where it is possible); AND Patient must have (as an initiating patient)/have had (as a continuing patient) more than one type of generalised seizures; AND Patient must have had at least two drop seizures (atonic, tonic or tonic-clonic) per week that are not adequately controlled with at least two other anti-epileptic drugs prior to initiating treatment with this medicine; AND The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs. Must be treated by a neurologist if treatment is being initiated; OR Must be treated by a neurologist if treatment is being continued or re-initiated; OR Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; OR Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued. Tonic seizures must have been recorded on video-EEG or have been clearly observed and reported by a witness. Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Certolizumab pegol
   * 1. *omit:*

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|  | C12354 | P12354 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; 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. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) 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. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within 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. | Compliance with Written Authority Required procedures |
|  | C12366 | P12366 |  | Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing 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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); 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; 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. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |

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|  | C12393 | P12393 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) - 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 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) restriction to complete 24 weeks treatment, depending on the dosage regimen; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Ciclosporin
   * 1. *omit:*

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|  | C12284 |  |  | Chronic severe dry eye disease with keratitis Continuing treatment Patient must have received PBS-subsidised treatment with this drug for this condition; AND The condition must have improved to an extent that corneal fluorescein staining, using the same scale used at the time of the first authority application, shows an improvement (reduction) by at least 3 grades from baseline (the grade stated in the first authority application) - the improvement need only be demonstrated by staining once only with the first Continuing treatment authority application; AND The condition must have improved to an extent that the patient's ocular surface disease index score at the time of this authority application, has improved (reduced) by at least 30% compared to the value stated in the first authority application (i.e. baseline). Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; OR Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines. Prescribing instructions: State in the first continuing treatment authority application for this drug: (i) an improved corneal fluorescein staining grade (a numerical value that has improved by 3 grades from that provided in the first Initial 1 treatment authority application). State in all continuing treatment authority applications: (ii) the ocular surface disease index score at the time of this authority application (a numerical value that is at least 30% lower than that stated in the first Initial 1 treatment authority application). | Compliance with Authority Required procedures |
|  | C12346 |  |  | Chronic severe dry eye disease with keratitis Initial treatment for up to the first 180 days of treatment Patient must have a corneal fluorescein staining (CFS) grade of 4 at treatment initiation, using at least one of: (i) the Oxford scale, (ii) the modified Oxford scale, (iii) an equivalent scale to the Oxford scale as determined by the prescriber; AND Patient must have an ocular surface disease index (OSDI) score of at least 23 at treatment initiation; AND The condition must be inadequately controlled by monotherapy with a preservative free artificial tears substitute. Patient must be undergoing simultaneous treatment with a preservative free artificial tears substitute; AND Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; OR Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines; AND Patient must not be undergoing treatment with this drug under this treatment phase beyond day 180 of treatment. Patient must be at least 18 years of age. Prescribing instruction: State in the first authority application for this drug, for the purpose of having a baseline measurement to assess response to treatment under the Continuing treatment listing, each of: (i) the qualifying corneal fluorescein staining grade (a numerical value no less than 4), (ii) the qualifying ocular surface disease index score (a numerical value no less than 23). | Compliance with Authority Required procedures |

* + 1. *insert* *in numerical order after existing text:*

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|  | C14026 |  |  | Chronic severe dry eye disease with keratitis Initial treatment for up to the first 180 days of treatment Patient must have a corneal fluorescein staining (CFS) grade of 4 at treatment initiation, using at least one of: (i) the Oxford scale, (ii) the modified Oxford scale, (iii) an equivalent scale to the Oxford scale as determined by the prescriber; AND Patient must have an ocular surface disease index (OSDI) score of at least 23 at treatment initiation; AND The condition must be inadequately controlled by monotherapy with a preservative free artificial tears substitute; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be undergoing simultaneous treatment with a preservative free artificial tears substitute; AND Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; OR Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines; AND Patient must not be undergoing treatment with this drug under this treatment phase beyond day 180 of treatment. Patient must be at least 18 years of age. Prescribing instruction: State in the first authority application for this drug, for the purpose of having a baseline measurement to assess response to treatment under the Continuing treatment listing, each of: (i) the qualifying corneal fluorescein staining grade (a numerical value no less than 4), (ii) the qualifying ocular surface disease index score (a numerical value no less than 23). | Compliance with Authority Required procedures |
|  | C14032 |  |  | Chronic severe dry eye disease with keratitis Continuing treatment Patient must have received PBS-subsidised treatment with this drug for this condition; AND The condition must have improved to an extent that corneal fluorescein staining, using the same scale used at the time of the first authority application, shows an improvement (reduction) by at least 3 grades from baseline (the grade stated in the first authority application) - the improvement need only be demonstrated by staining once only with the first Continuing treatment authority application; AND The condition must have improved to an extent that the patient's ocular surface disease index score at the time of this authority application, has improved (reduced) by at least 30% compared to the value stated in the first authority application (i.e. baseline); AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; OR Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines. Prescribing instructions: State in the first continuing treatment authority application for this drug: (i) an improved corneal fluorescein staining grade (a numerical value that has improved by 3 grades from that provided in the first Initial 1 treatment authority application). State in all continuing treatment authority applications: (ii) the ocular surface disease index score at the time of this authority application (a numerical value that is at least 30% lower than that stated in the first Initial 1 treatment authority application). | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, omit entry for Dipyridamole with aspirin
2. Schedule 4, Part 1, entry for Etanercept
   1. *omit:*

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|  | C12354 | P12354 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; 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. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) 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. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within 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. | Compliance with Written Authority Required procedures |
|  | C12359 | P12359 |  | Severe active juvenile idiopathic arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing 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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |
|  | C12366 | P12366 |  | Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing 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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); 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; 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. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |
|  | C12389 | P12389 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Golimumab
   1. *omit:*

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|  | C12401 | P12401 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; 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 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. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) 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. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within 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. | Compliance with Written Authority Required procedures |
|  | C12468 | P12468 |  | Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing 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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); 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; 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; 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. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Infliximab
   1. *omit:*

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|  | C12363 | P12363 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) - 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 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) restriction, with subcutaneous form restriction to complete 22 weeks initial treatment (intravenous and subcutaneous inclusive); AND The treatment must provide no more than the balance of up to 22 weeks treatment available under the - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) - subcutaneous form. Patient must be aged 18 years or older. | Compliance with Authority Required procedures |
|  | C12378 | P12378 |  | Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing 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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; 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. 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 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. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |
|  | C12390 | P12390 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - Change of treatment due to critical shortage of tocilizumab) - subcutaneous form at weeks 6, 8, 10, 12, 14 and 16 Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must have received 2 intravenous infusions with this drug for this condition at weeks 0 and 2 under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); 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 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. 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 authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) 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. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within 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. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Lenvatinib
   1. *insert in numerical order after existing text:*

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|  | C14041 | P14041 |  | Advanced, metastatic or recurrent endometrial carcinoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; OR Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose. | Compliance with Authority Required procedures - Streamlined Authority Code 14041 |
|  | C14042 | P14042 |  | Advanced, metastatic or recurrent endometrial carcinoma Initial treatment Patient must have received prior treatment with platinum-based chemotherapy; AND The condition must be untreated with each of: (i) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (ii) tyrosine kinase inhibitor therapy; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation. Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 14042 |
|  | C14043 | P14043 |  | Advanced, metastatic or recurrent endometrial carcinoma Transitioning from non-PBS to PBS-subsided treatment - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023; AND The treatment must be occurring in a patient where each of the following is true: (i) the patient had received prior treatment with platinum-based chemotherapy, (ii) the patient was untreated at treatment initiation with each of: (a) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (b) tyrosine kinase inhibitor therapy, (iii) the patient's WHO performance status was no higher than 1 at treatment initiation, (iv) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (c) as monotherapy after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose, (v) disease progression has not occurred whilst on treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 14043 |

1. Schedule 4, Part 1, entry for Nicotine
   1. *substitute:*

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| Nicotine | C5140 |  |  | Nicotine dependence Patient must be an Aboriginal or a Torres Strait Islander person. The treatment must be the sole PBS-subsidised therapy for this condition. |  |
|  | C14040 |  |  | Nicotine dependence The treatment must be as an aid to achieving abstinence from smoking; AND The treatment must not be a PBS-benefit with other non-nicotine drugs that are PBS indicated for smoking cessation; AND Patient must have indicated they are ready to cease smoking; AND Patient must not receive more than 2 x 12-week PBS-subsidised treatment courses per 12 month period. Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated. Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated. |  |

1. Schedule 4, Part 1, entry for Pembrolizumab
   1. *insert in numerical order after existing text:*

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|  | C14027 |  |  | Advanced, metastatic or recurrent endometrial carcinoma Initial treatment Patient must have received prior treatment with platinum-based chemotherapy; AND The condition must be untreated with each of: (i) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (ii) tyrosine kinase inhibitor therapy; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation. Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions. | Compliance with Authority Required procedures - Streamlined Authority Code 14027 |
|  | C14028 |  |  | Advanced, metastatic or recurrent endometrial carcinoma Transitioning from non-PBS to PBS-subsided supply - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023; AND The treatment must be occurring in a patient where each of the following is true: (i) the patient had received prior treatment with platinum-based chemotherapy, (ii) the patient was untreated at treatment initiation with each of: (a) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (b) tyrosine kinase inhibitor therapy, (iii) the patient's WHO performance status was no higher than 1 at treatment initiation, (iv) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (v) disease progression has not occurred whilst on treatment, (vi) this prescription does not extend treatment beyond 24 months from the first administered dose. Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions. | Compliance with Authority Required procedures - Streamlined Authority Code 14028 |
|  | C14044 |  |  | Advanced, metastatic or recurrent endometrial carcinoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime. | Compliance with Authority Required procedures - Streamlined Authority Code 14044 |

1. Schedule 4, Part 1, omit entry for Risedronic acid and calcium
2. Schedule 4, Part 1, entry for Selinexor
   1. *substitute:*

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| Selinexor | C13161 | P13161 |  | Relapsed and/or refractory multiple myeloma Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 160 mg per week Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2022; AND The treatment must be in combination with dexamethasone; AND Patient must have progressive disease after at least four prior lines of therapy, prior to initiating non-PBS-subsidised therapy with this drug for this condition; AND Patient must have demonstrated refractory disease to prior treatments, prior to initiating non-PBS-subsidised therapy with this drug for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody; AND Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | Compliance with Authority Required procedures |
|  | C14021 | P14021 |  | Relapsed and/or refractory multiple myeloma Initial treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week The condition must be confirmed by a histological diagnosis; AND Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND Patient must have progressive disease after at least one prior therapy; AND Patient must not have previously received this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records. Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records: (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy | Compliance with Authority Required procedures |
|  | C14022 | P14022 |  | Relapsed and/or refractory multiple myeloma Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 80 mg, 60 mg or 40 mg per week Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023; AND Patient must have met all initial treatment PBS eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are: (a) the condition was confirmed by histological diagnosis, (b) the treatment is/was being used as part of combination therapy limited to this drug in combination with either: (i) dexamethasone, (ii) dexamethasone plus bortezomib, (c) the condition progressed (see definition of progressive disease below) after at least one prior therapy, (d) the patient had never been treated with this drug; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | Compliance with Authority Required procedures |
|  | C14023 | P14023 |  | Relapsed and/or refractory multiple myeloma Continuing treatment - Dose requirement of 100 mg per week Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | Compliance with Authority Required procedures |
|  | C14024 | P14024 |  | Relapsed and/or refractory multiple myeloma Initial treatment - Dose requirement of 100 mg per week The condition must be confirmed by a histological diagnosis; AND Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND Patient must have progressive disease after at least one prior therapy; AND Patient must not have previously received this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy | Compliance with Authority Required procedures |
|  | C14031 | P14031 |  | Relapsed and/or refractory multiple myeloma Continuing treatment - Dose requirement of 160 mg per week Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | Compliance with Authority Required procedures |
|  | C14037 | P14037 |  | Relapsed and/or refractory multiple myeloma Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 100 mg per week Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023; AND Patient must have met all initial treatment PBS eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are: (a) the condition was confirmed by histological diagnosis, (b) the treatment is/was being used as part of combination therapy limited to this drug in combination with either: (i) dexamethasone, (ii) dexamethasone plus bortezomib, (c) the condition progressed (see definition of progressive disease below) after at least one prior therapy, (d) the patient had never been treated with this drug; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | Compliance with Authority Required procedures |
|  | C14039 | P14039 |  | Relapsed and/or refractory multiple myeloma Initial treatment - Dose requirement of 160 mg per week The condition must be confirmed by a histological diagnosis; AND Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND Patient must have progressive disease after at least one prior therapy; AND Patient must not have previously received this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy | Compliance with Authority Required procedures |
|  | C14045 | P14045 |  | Relapsed and/or refractory multiple myeloma Continuing treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Tofacitinib
   1. *omit:*

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|  | C12354 | P12354 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; 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. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) 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. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within 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. | Compliance with Written Authority Required procedures |
|  | C12366 | P12366 |  | Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing 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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); 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; 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. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Upadacitinib
   1. *omit:*

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|  | C12354 | P12354 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; 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. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) 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. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within 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. | Compliance with Written Authority Required procedures |
|  | C12366 | P12366 |  | Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing 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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); 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; 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. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |

1. Schedule 5, entry for Amoxicillin with clavulanic acid
   1. *substitute:*

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| Amoxicillin with clavulanic acid | GRP-26768 | Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) | Oral | AMCLAVOX DUO FORTE 875/125 APO-AMOXY/CLAV 875/125 APO-Amoxycillin and Clavulanic Acid APX-Amoxicillin/Clavulanic Acid AlphaClav Duo Forte AmoxyClav generichealth 875/125 Amoxyclav AN 875/125 Augmentin Duo forte Curam Duo Forte 875/125 |
|  |  | Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (s19A) | Oral | Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Medsurge) Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals) Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs) |

1. 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)
   1. *insert:*

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| Cefalexin | GRP-27406 | Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL | Oral | Cefalexin Sandoz Ibilex 250 Keflex |
|  |  | Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL (s19A) | Oral | Keforal |

1. Schedule 5, after entry for Desvenlafaxine in the form Tablet (modified release) 50 mg (as benzoate) *[GRP-16220]*
   1. *insert:*

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| --- | --- | --- | --- | --- |
| Disopyramide | GRP-27397 | Capsule 100 mg | Oral | Rythmodan |
|  |  | Capsule 100 mg (s19A) | Oral | Rythmodan (Canada) |

1. Schedule 5, after entry for Lansoprazole in the form Tablet 30 mg (orally disintegrating)
   1. *insert:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Larotrectinib | GRP-27403 | Oral solution 20 mg per mL (as sulfate), 50 mL, 2 | Oral | VITRAKVI |
|  |  | Oral solution 20 mg per mL (as sulfate), 100 mL | Oral | Vitrakvi |

1. Schedule 5, after entry for Methylprednisolone in the form Powder for injection 40 mg (as sodium succinate) with diluent
   1. *insert:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Minoxidil | GRP-27410 | Tablet 10 mg | Oral | Loniten |
|  |  | Tablet 10 mg (s19A) | Oral | Minoxidil 10 mg (Roma Pharmaceuticals) |

1. Schedule 5, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg *[GRP-15402]*
   1. *omit from the column headed “Brand”:* ODT Ondansetron GH
2. Schedule 5, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg *[GRP-15983]*
   1. *omit from the column headed “Brand”:* ODT Ondansetron GH
3. Schedule 5, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg *[GRP-16933]*
   1. *omit from the column headed “Brand”:* ODT Ondansetron GH
4. Schedule 5, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg *[GRP-17042]*
   1. *omit from the column headed “Brand”:* ODT Ondansetron GH
5. Schedule 5, after entry for Perindopril with indapamide in the form Tablet containing perindopril arginine 5 mg with indapamide hemihydrate 1.25 mg
   1. *insert:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Phenoxymethylpenicillin | GRP-27408 | Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL | Oral | Phenoxymethylpenicillin-AFT |
|  |  | Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL (s19A) | Oral | Penopen |

1. Schedule 5, entry for Tenofovir with emtricitabine in the form Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg
   1. *insert in alphabetical order in the column headed “Brand”:* Tenofovir Disoproxil Emtricitabine Viatris 300/200