

**PB 52 of 2024**

**National Health (Listing of Pharmaceutical Benefits) Amendment (June Update) Instrument 2024**

*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 2024

**NIKOLAI TSYGANOV**

Assistant Secretary

Pricing and PBS Policy Branch

Technology Assessment and Access Division

Contents

1 Name 1

2 Commencement 1

3 Authority 1

4 Schedules 1

Schedule 1—Amendments 2

National Health (Listing of Pharmaceutical Benefits) Instrument 2024   
(PB 26 of 2024). 2

1 Name

1. This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (June Update) Instrument 2024*.
2. This Instrument may also be cited as PB 52 of 2024.

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 2024* | *1 June 2024* |

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 2024 (PB 26 of 2024)*

1. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Brands: Adalicip; Humira; and Yuflyma; Maximum Quantity: 6; Number of Repeats: 0]*
2. *omit from the column headed “Circumstances”:* **C12275 C12336**
3. *insert in numerical order in the column headed “Circumstances”:* **C15249 C15309 C15319**
4. *omit from the column headed “Purposes”:* **P12275 P12336**
5. *insert in numerical order in the column headed “Purposes”:* **P15249 P15309 P15319**
6. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brands: Amgevita; Hadlima; Hyrimoz; and Idacio; Maximum Quantity: 6; Number of Repeats: 0]*
7. *omit from the column headed “Circumstances”:* **C12275 C12336**
8. *insert in numerical order in the column headed “Circumstances”:* **C15249 C15309 C15319**
9. *omit from the column headed “Purposes”:* **P12275 P12336**
10. *insert in numerical order in the column headed “Purposes”:* **P15249 P15309 P15319**
11. Schedule 1, Part 1, entry for Adalimumab in each of the forms: Injection 80 mg in 0.8 mL pre-filled pen; and Injection 80 mg in 0.8 mL pre-filled syringe *[Maximum Quantity: 3; Number of Repeats: 0]*
12. *omit from the column headed “Circumstances”:* **C12275 C12278**
13. *insert in numerical order in the column headed “Circumstances”:* **C15249 C15309 C15319**
14. *omit from the column headed “Purposes”:* **P12275 P12278**
15. *insert in numerical order in the column headed “Purposes”:* **P15249 P15309 P15319**
16. Schedule 1, Part 1, entry for Alogliptin in the form Tablet 6.25 mg (as benzoate) *[Maximum Quantity: 28; Number of Repeats: 5]*
17. *omit from the column headed “Circumstances”:* C4349 *substitute:* C15261
18. *omit from the column headed “Purposes”:* P4349 *substitute:* P15261
19. Schedule 1, Part 1, entry for Alogliptin in the form Tablet 6.25 mg (as benzoate) *[Maximum Quantity: 56; Number of Repeats: 5]*
20. *omit from the column headed “Circumstances”:* C14862 *substitute:* C15287
21. *omit from the column headed “Purposes”:* P14862 *substitute:* P15287
22. Schedule 1, Part 1, entry for Alogliptin in the form Tablet 12.5 mg (as benzoate) *[Maximum Quantity: 28; Number of Repeats: 5]*
23. *omit from the column headed “Circumstances”:* C4349 *substitute:* C15261
24. *omit from the column headed “Purposes”:* P4349 *substitute:* P15261
25. Schedule 1, Part 1, entry for Alogliptin in the form Tablet 12.5 mg (as benzoate) *[Maximum Quantity: 56; Number of Repeats: 5]*
26. *omit from the column headed “Circumstances”:* C14862 *substitute:* C15287
27. *omit from the column headed “Purposes”:* P14862 *substitute:* P15287
28. Schedule 1, Part 1, entry for Alogliptin in the form Tablet 25 mg (as benzoate) *[Maximum Quantity: 28; Number of Repeats: 5]*
29. *omit from the column headed “Circumstances”:* C4349 *substitute:* C15261
30. *omit from the column headed “Purposes”:* P4349 *substitute:* P15261
31. Schedule 1, Part 1, entry for Alogliptin in the form Tablet 25 mg (as benzoate) *[Maximum Quantity: 56; Number of Repeats: 5]*
32. *omit from the column headed “Circumstances”:* C14862 *substitute:* C15287
33. *omit from the column headed “Purposes”:* P14862 *substitute:* P15287
34. Schedule 1, Part 1, entry for Alogliptin with metformin in the form Tablet containing 12.5 mg alogliptin (as benzoate) with 1 g metformin hydrochloride *[Maximum Quantity: 56; Number of Repeats: 5]*
35. *omit from the column headed “Circumstances”:* C4423 C4427 *substitute:* C15276
36. *omit from the column headed “Purposes”:* P4423 P4427 *substitute:* P15276
37. Schedule 1, Part 1, entry for Alogliptin with metformin in the form Tablet containing 12.5 mg alogliptin (as benzoate) with 1 g metformin hydrochloride *[Maximum Quantity: 112; Number of Repeats: 5]*
38. *omit from the column headed “Circumstances”:* C14876 *substitute:* C15288
39. *omit from the column headed “Purposes”:* P14876 *substitute:* P15288
40. Schedule 1, Part 1, entry for Alogliptin with metformin in the form Tablet containing 12.5 mg alogliptin (as benzoate) with 500 mg metformin hydrochloride *[Maximum Quantity: 56; Number of Repeats: 5]*
41. *omit from the column headed “Circumstances”:* C4423 C4427 *substitute:* C15276
42. *omit from the column headed “Purposes”:* P4423 P4427 *substitute:* P15276
43. Schedule 1, Part 1, entry for Alogliptin with metformin in the form Tablet containing 12.5 mg alogliptin (as benzoate) with 500 mg metformin hydrochloride *[Maximum Quantity: 112; Number of Repeats: 5]*
44. *omit from the column headed “Circumstances”:* C14876 *substitute:* C15288
45. *omit from the column headed “Purposes”:* P14876 *substitute:* P15288
46. Schedule 1, Part 1, entry for Alogliptin with metformin in the form Tablet containing 12.5 mg alogliptin (as benzoate) with 850 mg metformin hydrochloride *[Maximum Quantity: 56; Number of Repeats: 5]*
47. *omit from the column headed “Circumstances”:* C4423 C4427 *substitute:* C15276
48. *omit from the column headed “Purposes”:* P4423 P4427 *substitute:* P15276
49. Schedule 1, Part 1, entry for Alogliptin with metformin in the form Tablet containing 12.5 mg alogliptin (as benzoate) with 850 mg metformin hydrochloride *[Maximum Quantity: 112; Number of Repeats: 5]*
50. *omit from the column headed “Circumstances”:* C14876 *substitute:* C15288
51. *omit from the column headed “Purposes”:* P14876 *substitute:* P15288
52. Schedule 1, Part 1, entry for Ambrisentan in the form Tablet 5 mg
    1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ambrisentan | Tablet 5 mg | Oral | Ambrisentan Mylan | AF | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 30 |  | D(100) |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Anastrozole | Tablet 1 mg | Oral | Arimidex | AP | MP NP | C5464 | P5464 | 30 | 5 |  | 30 |  |  |
| Anastrozole | Tablet 1 mg | Oral | Arimidex | AP | MP NP | C14943 | P14943 | 60 | 5 |  | 30 |  |  |

1. Schedule 1, Part 1, entry for Apremilast in each of the forms: Pack containing 4 tablets 10 mg, 4 tablets 20 mg and 19 tablets 30 mg; and Tablet 30 mg

*omit from the column headed “Circumstances”:* C14417 *substitute:* C15326

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Azacitidine | Powder for injection 100 mg | Injection | Azacitidine Accord | OC | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | PB(100) |
| Azacitidine | Powder for injection 100 mg | Injection | Azacitidine Dr.Reddy's | RI | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | PB(100) |
| Azacitidine | Powder for injection 100 mg | Injection | AZACITIDINE EUGIA | YG | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | PB(100) |
| Azacitidine | Powder for injection 100 mg | Injection | Azacitidine Juno | JO | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | PB(100) |
| Azacitidine | Powder for injection 100 mg | Injection | Azacitidine MSN | JU | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | PB(100) |
| Azacitidine | Powder for injection 100 mg | Injection | Azacitidine Sandoz | SZ | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | PB(100) |
| Azacitidine | Powder for injection 100 mg | Injection | Azacitidine-Teva | TB | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | PB(100) |
| Azacitidine | Tablet 200 mg | Oral | Onureg | CJ | MP | C14338 |  | 14 | 2 |  | 7 |  |  |
| Azacitidine | Tablet 300 mg | Oral | Onureg | CJ | MP | C14332 C14338 | P14332 P14338 | 14 | 2 |  | 7 |  |  |
| Azacitidine | Tablet 300 mg | Oral | Onureg | CJ | MP | C14323 | P14323 | 21 | 1 |  | 7 |  |  |

1. Schedule 1, Part 1, entry for Benzathine benzylpenicillin
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Benzathine benzylpenicillin | Injection containing 1,200,000 units benzathine benzylpenicillin tetrahydrate in 2.3 mL single use pre-filled syringe | Injection | Bicillin L-A | PF | PDP MP NP |  |  | 10 | 0 |  | 10 |  |  |
| Benzathine benzylpenicillin | Injection containing 600,000 units benzathine benzylpenicillin tetrahydrate in 1.17 mL single use pre-filled syringe | Injection | Bicillin L-A | PF | PDP MP NP |  |  | 10 | 0 |  | 10 |  |  |
| Benzathine benzylpenicillin | Powder for injection 1,200,000 units with diluent 5 mL (S19A) | Injection | Benzylpenicillin Benzathine (Brancaster Pharma, UK) | OJ | PDP MP NP |  |  | 10 | 0 |  | 1 |  |  |
| Benzathine benzylpenicillin | Powder for injection 1,200,000 units with diluent 5 mL (S19A) | Injection | Extencilline Benzathine Benzylpenicillin (France) | YO | PDP MP NP |  |  | 10 | 0 |  | 1 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bisacodyl | Enemas 10 mg in 5 mL, 25 | Rectal | Bisalax | OX | MP NP | C5613 C5640 C5685 C5720 C5775 C5776 C5804 |  | 1 | 2 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Bortezomib in the form Powder for injection 1 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bortezomib | Powder for injection 1 mg | Injection | Velcade | JC | MP | C11099 C13745 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

1. Schedule 1, Part 1, entry for Bortezomib in the form Powder for injection 3 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bortezomib | Powder for injection 3 mg | Injection | Velcade | JC | MP | C11099 C13745 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

1. Schedule 1, Part 1, entry for Bortezomib in the form Powder for injection 3.5 mg
2. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bortezomib | Powder for injection 3.5 mg | Injection | BORTEZOMIB EUGIA | YG | MP | C11099 C13745 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bortezomib | Powder for injection 3.5 mg | Injection | Velcade | JC | MP | C11099 C13745 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bosentan | Tablet 62.5 mg (as monohydrate) | Oral | Bosentan APO | GX | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 60 |  | D(100) |
| Bosentan | Tablet 62.5 mg (as monohydrate) | Oral | BOSENTAN DR.REDDY'S | RI | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 60 |  | D(100) |
| Bosentan | Tablet 62.5 mg (as monohydrate) | Oral | Bosentan Mylan | AF | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 60 |  | D(100) |
| Bosentan | Tablet 62.5 mg (as monohydrate) | Oral | Bosentan RBX | RA | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 60 |  | D(100) |
| Bosentan | Tablet 62.5 mg (as monohydrate) | Oral | BOSLEER | RW | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 60 |  | D(100) |
| Bosentan | Tablet 125 mg (as monohydrate) | Oral | Bosentan APO | GX | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 60 |  | D(100) |
| Bosentan | Tablet 125 mg (as monohydrate) | Oral | Bosentan Cipla | LR | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 60 |  | D(100) |
| Bosentan | Tablet 125 mg (as monohydrate) | Oral | BOSENTAN DR.REDDY'S | RI | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 60 |  | D(100) |
| Bosentan | Tablet 125 mg (as monohydrate) | Oral | Bosentan GH | GQ | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 60 |  | D(100) |
| Bosentan | Tablet 125 mg (as monohydrate) | Oral | Bosentan Mylan | AF | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 60 |  | D(100) |
| Bosentan | Tablet 125 mg (as monohydrate) | Oral | Bosentan RBX | RA | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 60 |  | D(100) |
| Bosentan | Tablet 125 mg (as monohydrate) | Oral | BOSLEER | RW | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 60 |  | D(100) |

1. Schedule 1, Part 1, entry for Budesonide with formoterol
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 100 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | Inhalation by mouth | Symbicort Turbuhaler 100/6 | AP | MP | C10538 |  | 1 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 100 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | Inhalation by mouth | Symbicort Turbuhaler 100/6 | AP | MP NP | C4380 |  | 1 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 60 doses | Inhalation by mouth | Bufomix Easyhaler 200/6 | OX | MP NP | C10464 | P10464 | 2 | 2 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 60 doses | Inhalation by mouth | Bufomix Easyhaler 200/6 | OX | MP NP | C7970 | P7970 | 2 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 60 doses | Inhalation by mouth | Bufomix Easyhaler 200/6 | OX | MP | C10538 | P10538 | 2 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | Inhalation by mouth | BiResp Spiromax | TB | MP NP | C10464 | P10464 | 1 | 2 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | Inhalation by mouth | BiResp Spiromax | TB | MP NP | C7970 | P7970 | 1 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | Inhalation by mouth | BiResp Spiromax | TB | MP | C10538 | P10538 | 1 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | Inhalation by mouth | DuoResp Spiromax | EV | MP NP | C10464 | P10464 | 1 | 2 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | Inhalation by mouth | DuoResp Spiromax | EV | MP NP | C7970 | P7970 | 1 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | Inhalation by mouth | DuoResp Spiromax | EV | MP | C10538 | P10538 | 1 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | Inhalation by mouth | Rilast TURBUHALER 200/6 | XT | MP NP | C10464 | P10464 | 1 | 2 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | Inhalation by mouth | Rilast TURBUHALER 200/6 | XT | MP NP | C7970 | P7970 | 1 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | Inhalation by mouth | Rilast TURBUHALER 200/6 | XT | MP | C10538 | P10538 | 1 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | Inhalation by mouth | Symbicort Turbuhaler 200/6 | AP | MP NP | C10464 | P10464 | 1 | 2 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | Inhalation by mouth | Symbicort Turbuhaler 200/6 | AP | MP NP | C7970 | P7970 | 1 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | Inhalation by mouth | Symbicort Turbuhaler 200/6 | AP | MP | C10538 | P10538 | 1 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses | Inhalation by mouth | BiResp Spiromax | TB | MP NP | C7979 C10121 |  | 2 | 5 |  | 2 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses | Inhalation by mouth | Bufomix Easyhaler 400/12 | OX | MP NP | C7979 C10121 |  | 2 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses | Inhalation by mouth | DuoResp Spiromax | EV | MP NP | C7979 C10121 |  | 2 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses | Inhalation by mouth | DuoResp Spiromax | EV | MP NP | C7979 C10121 |  | 2 | 5 |  | 2 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses | Inhalation by mouth | Rilast TURBUHALER 400/12 | XT | MP NP | C7979 C10121 |  | 2 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses | Inhalation by mouth | Symbicort TURBUHALER 400/12 | AP | MP NP | C7979 C10121 |  | 2 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Pressurised inhalation containing budesonide 50 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses | Inhalation by mouth | Symbicort Rapihaler 50/3 | AP | MP NP | C4397 |  | 2 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Pressurised inhalation containing budesonide 50 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses | Inhalation by mouth | Symbicort Rapihaler 50/3 | AP | MP | C10538 |  | 2 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses | Inhalation by mouth | Rilast RAPIHALER 100/3 | XT | MP NP | C10482 | P10482 | 2 | 2 |  | 1 |  |  |
| Budesonide with formoterol | Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses | Inhalation by mouth | Rilast RAPIHALER 100/3 | XT | MP NP | C4397 | P4397 | 2 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses | Inhalation by mouth | Rilast RAPIHALER 100/3 | XT | MP | C10538 | P10538 | 2 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses | Inhalation by mouth | Symbicort Rapihaler 100/3 | AP | MP NP | C10482 | P10482 | 2 | 2 |  | 1 |  |  |
| Budesonide with formoterol | Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses | Inhalation by mouth | Symbicort Rapihaler 100/3 | AP | MP NP | C4397 | P4397 | 2 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses | Inhalation by mouth | Symbicort Rapihaler 100/3 | AP | MP | C10538 | P10538 | 2 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Pressurised inhalation containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | Inhalation by mouth | Rilast RAPIHALER 200/6 | XT | MP NP | C4404 C10121 |  | 2 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Pressurised inhalation containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | Inhalation by mouth | Rilast RAPIHALER 200/6 | XT | MP | C10538 |  | 2 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Pressurised inhalation containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | Inhalation by mouth | Symbicort Rapihaler 200/6 | AP | MP NP | C4404 C10121 |  | 2 | 5 |  | 1 |  |  |
| Budesonide with formoterol | Pressurised inhalation containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | Inhalation by mouth | Symbicort Rapihaler 200/6 | AP | MP | C10538 |  | 2 | 5 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Cefepime in the form Powder for injection 1 g (as hydrochloride)
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cefepime | Powder for injection 1 g (as hydrochloride) | Injection | Omegapharm Pty Ltd | OE | MP NP | C5842 |  | 10 | 0 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Cefepime in the form Powder for injection 2 g (as hydrochloride)
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cefepime | Powder for injection 2 g (as hydrochloride) | Injection | Omegapharm Pty Ltd | OE | MP NP | C5842 |  | 10 | 0 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Ceftriaxone in the form Powder for injection 1 g (as sodium)
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ceftriaxone | Powder for injection 1 g (as sodium) | Injection | Ceftriaxone Alphapharm | AF | MP NP | C5830 C5862 C5868 |  | 5 | 0 |  | 5 |  |  |
| Ceftriaxone | Powder for injection 1 g (as sodium) | Injection | Ceftriaxone Alphapharm | AF | MP NP | C5830 C5862 C5868 |  | 5 | 0 |  | 10 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dapagliflozin | Tablet 10 mg (as propanediol monohydrate) | Oral | Forxiga | AP | MP NP | C13230 C14471 C15047 C15311 | P13230 P14471 P15047 P15311 | 28 | 5 |  | 28 |  |  |
| Dapagliflozin | Tablet 10 mg (as propanediol monohydrate) | Oral | Forxiga | AP | MP NP | C15051 C15265 | P15051 P15265 | 56 | 5 |  | 56 |  |  |

1. Schedule 1, Part 1, entry for Dapagliflozin with metformin
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dapagliflozin with metformin | Tablet (modified release) containing 5 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride | Oral | Xigduo XR 5/1000 | AP | MP NP | C15289 | P15289 | 56 | 5 |  | 56 |  |  |
| Dapagliflozin with metformin | Tablet (modified release) containing 5 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride | Oral | Xigduo XR 5/1000 | AP | MP NP | C15267 | P15267 | 112 | 5 |  | 56 |  |  |
| Dapagliflozin with metformin | Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride | Oral | Xigduo XR 10/1000 | AP | MP NP | C15289 | P15289 | 28 | 5 |  | 28 |  |  |
| Dapagliflozin with metformin | Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride | Oral | Xigduo XR 10/1000 | AP | MP NP | C15267 | P15267 | 56 | 5 |  | 28 |  |  |
| Dapagliflozin with metformin | Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 500 mg metformin hydrochloride | Oral | Xigduo XR 10/500 | AP | MP NP | C15289 | P15289 | 28 | 5 |  | 28 |  |  |
| Dapagliflozin with metformin | Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 500 mg metformin hydrochloride | Oral | Xigduo XR 10/500 | AP | MP NP | C15267 | P15267 | 56 | 5 |  | 28 |  |  |

1. Schedule 1, Part 1, entry for Deucravacitinib

*omit from the column headed “Circumstances”:* **C14384** *substitute:* **C15330**

1. Schedule 1, Part 1, entry for Dicloxacillin in the form Capsule 250 mg (as sodium)
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dicloxacillin | Capsule 250 mg (as sodium) | Oral | DICLOXACILLIN VIATRIS 250 | MQ | PDP | C5268 |  | 24 | 0 |  | 24 |  |  |
| Dicloxacillin | Capsule 250 mg (as sodium) | Oral | DICLOXACILLIN VIATRIS 250 | MQ | MP NP MW | C5415 |  | 24 | 0 |  | 24 |  |  |

1. Schedule 1, Part 1, entry for Dosulepin in the form Capsule containing dosulepin hydrochloride 25 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dosulepin | Capsule containing dosulepin hydrochloride 25 mg | Oral | Dosulepin Mylan | AL | MP NP |  |  | 50 | 2 |  | 50 |  |  |

1. Schedule 1, Part 1, entry for Dulaglutide

*omit from the column headed “Circumstances”:* C5469 C5478 C7645 *substitute:* C15263 C15301

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Empagliflozin | Tablet 10 mg | Oral | Jardiance | BY | MP NP | C13230 C14471 C15047 C15311 | P13230 P14471 P15047 P15311 | 30 | 5 |  | 30 |  |  |
| Empagliflozin | Tablet 10 mg | Oral | Jardiance | BY | MP NP | C15051 C15265 | P15051 P15265 | 60 | 5 |  | 30 |  |  |
| Empagliflozin | Tablet 25 mg | Oral | Jardiance | BY | MP NP | C15311 | P15311 | 30 | 5 |  | 30 |  |  |
| Empagliflozin | Tablet 25 mg | Oral | Jardiance | BY | MP NP | C15265 | P15265 | 60 | 5 |  | 30 |  |  |

1. Schedule 1, Part 1, entry for Empagliflozin with linagliptin
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Empagliflozin with linagliptin | Tablet containing 10 mg empagliflozin with 5 mg linagliptin | Oral | Glyxambi | BY | MP NP | C15269 | P15269 | 30 | 5 |  | 30 |  |  |
| Empagliflozin with linagliptin | Tablet containing 10 mg empagliflozin with 5 mg linagliptin | Oral | Glyxambi | BY | MP NP | C15270 | P15270 | 60 | 5 |  | 30 |  |  |
| Empagliflozin with linagliptin | Tablet containing 25 mg empagliflozin with 5 mg linagliptin | Oral | Glyxambi | BY | MP NP | C15269 | P15269 | 30 | 5 |  | 30 |  |  |
| Empagliflozin with linagliptin | Tablet containing 25 mg empagliflozin with 5 mg linagliptin | Oral | Glyxambi | BY | MP NP | C15270 | P15270 | 60 | 5 |  | 30 |  |  |

1. Schedule 1, Part 1, entry for Empagliflozin with metformin
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Empagliflozin with metformin | Tablet containing 5 mg empagliflozin with 1 g metformin hydrochloride | Oral | Jardiamet 5 mg/1000 mg | BY | MP NP | C15289 | P15289 | 60 | 5 |  | 60 |  |  |
| Empagliflozin with metformin | Tablet containing 5 mg empagliflozin with 1 g metformin hydrochloride | Oral | Jardiamet 5 mg/1000 mg | BY | MP NP | C15267 | P15267 | 120 | 5 |  | 60 |  |  |
| Empagliflozin with metformin | Tablet containing 5 mg empagliflozin with 500 mg metformin hydrochloride | Oral | Jardiamet 5 mg/500 mg | BY | MP NP | C15289 | P15289 | 60 | 5 |  | 60 |  |  |
| Empagliflozin with metformin | Tablet containing 5 mg empagliflozin with 500 mg metformin hydrochloride | Oral | Jardiamet 5 mg/500 mg | BY | MP NP | C15267 | P15267 | 120 | 5 |  | 60 |  |  |
| Empagliflozin with metformin | Tablet containing 12.5 mg empagliflozin with 1 g metformin hydrochloride | Oral | Jardiamet 12.5 mg/1000 mg | BY | MP NP | C15289 | P15289 | 60 | 5 |  | 60 |  |  |
| Empagliflozin with metformin | Tablet containing 12.5 mg empagliflozin with 1 g metformin hydrochloride | Oral | Jardiamet 12.5 mg/1000 mg | BY | MP NP | C15267 | P15267 | 120 | 5 |  | 60 |  |  |
| Empagliflozin with metformin | Tablet containing 12.5 mg empagliflozin with 500 mg metformin hydrochloride | Oral | Jardiamet 12.5 mg/500 mg | BY | MP NP | C15289 | P15289 | 60 | 5 |  | 60 |  |  |
| Empagliflozin with metformin | Tablet containing 12.5 mg empagliflozin with 500 mg metformin hydrochloride | Oral | Jardiamet 12.5 mg/500 mg | BY | MP NP | C15267 | P15267 | 120 | 5 |  | 60 |  |  |

1. Schedule 1, Part 1, entry for Enalapril in the form Tablet containing enalapril maleate 5 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Enalapril | Tablet containing enalapril maleate 5 mg | Oral | Enalapril generichealth | GQ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Enalapril | Tablet containing enalapril maleate 5 mg | Oral | Enalapril generichealth | GQ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

1. Schedule 1, Part 1, entry for Enalapril in the form Tablet containing enalapril maleate 10 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Enalapril | Tablet containing enalapril maleate 10 mg | Oral | Enalapril generichealth | GQ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Enalapril | Tablet containing enalapril maleate 10 mg | Oral | Enalapril generichealth | GQ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

1. Schedule 1, Part 1, entry for Estradiol in the form Transdermal patches 585 micrograms, 8
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Estradiol | Transdermal patches 585 micrograms, 8 | Transdermal | Estradiol Transdermal System (Sandoz, USA) | HX | MP NP |  |  | 1 | 5 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Estradiol in the form Transdermal patches 1.17 mg, 8
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Estradiol | Transdermal patches 1.17 mg, 8 | Transdermal | Estradiol Transdermal System (Sandoz, USA) | HX | MP NP |  |  | 1 | 5 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Estradiol in the form Transdermal patches 1.56 mg, 8
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Estradiol | Transdermal patches 1.56 mg, 8 | Transdermal | Estradiol Transdermal System (Sandoz, USA) | HX | MP NP |  |  | 1 | 5 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Furosemide in the form Tablet 20 mg
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Furosemide | Tablet 20 mg | Oral | UREMIDE 20 | AF | MP NP |  |  | 100 | 1 |  | 50 |  |  |
| Furosemide | Tablet 20 mg | Oral | UREMIDE 20 | AF | MP NP |  |  | 100 | 1 |  | 100 |  |  |
| Furosemide | Tablet 20 mg | Oral | UREMIDE 20 | AF | MP NP |  | P14238 | 200 | 1 |  | 50 |  |  |
| Furosemide | Tablet 20 mg | Oral | UREMIDE 20 | AF | MP NP |  | P14238 | 200 | 1 |  | 100 |  |  |

1. Schedule 1, Part 1, entry for Inclisiran in the form Injection 284 mg in 1.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 0]*
2. *insert in numerical order in the column headed “Circumstances”:* **C15313 C15323**
3. *insert in numerical order in the column headed “Purposes”:* **P15313 P15323**
4. Schedule 1, Part 1, entry for Inclisiran in the form Injection 284 mg in 1.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 1]*
5. *omit from the column headed “Circumstances”:* **C15122 C15132 C15144 C15153** *substitute:* **C15315 C15331**
6. *omit from the column headed “Purposes”:* **P15122 P15132 P15144 P15153** *substitute:* **P15315 P15331**
7. Schedule 1, Part 1, after entry for Ivabradine in the form Tablet 7.5 mg (as hydrochloride) *[Brand: Coralan]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ivacaftor | Sachet containing granules 25 mg | Oral | Kalydeco | VR | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 56 |  | D(100) |

1. Schedule 1, Part 1, omit entry for Ketoconazole
2. Schedule 1, Part 1, entry for Lamivudine with zidovudine
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lamivudine with zidovudine | Tablet 150 mg-300 mg | Oral | Lamivudine 150 mg + Zidovudine 300 mg Alphapharm | AF | MP NP | C4454 C4512 |  | 120 | 5 |  | 60 |  | D(100) |

1. Schedule 1, Part 1, entry for Lenvatinib in the form Capsule 4 mg (as mesilate) *[Maximum Quantity: 60; Number of Repeats: 2]*
2. *omit from the column headed “Circumstances”:* C14007
3. *omit from the column headed “Purposes”:* P14007
4. Schedule 1, Part 1, entry for Lenvatinib in the form Capsule 10 mg (as mesilate)

*omit from the column headed “Circumstances”:* C14007

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Linagliptin | Tablet 5 mg | Oral | Trajenta | BY | MP NP | C15261 | P15261 | 30 | 5 |  | 30 |  |  |
| Linagliptin | Tablet 5 mg | Oral | Trajenta | BY | MP NP | C15287 | P15287 | 60 | 5 |  | 30 |  |  |

1. Schedule 1, Part 1, entry for Linagliptin with metformin
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Linagliptin with metformin | Tablet containing 2.5 mg linagliptin with 1000 mg metformin hydrochloride | Oral | Trajentamet | BY | MP NP | C15276 | P15276 | 60 | 5 |  | 60 |  |  |
| Linagliptin with metformin | Tablet containing 2.5 mg linagliptin with 1000 mg metformin hydrochloride | Oral | Trajentamet | BY | MP NP | C15288 | P15288 | 120 | 5 |  | 60 |  |  |
| Linagliptin with metformin | Tablet containing 2.5 mg linagliptin with 500 mg metformin hydrochloride | Oral | Trajentamet | BY | MP NP | C15276 | P15276 | 60 | 5 |  | 60 |  |  |
| Linagliptin with metformin | Tablet containing 2.5 mg linagliptin with 500 mg metformin hydrochloride | Oral | Trajentamet | BY | MP NP | C15288 | P15288 | 120 | 5 |  | 60 |  |  |
| Linagliptin with metformin | Tablet containing 2.5 mg linagliptin with 850 mg metformin hydrochloride | Oral | Trajentamet | BY | MP NP | C15276 | P15276 | 60 | 5 |  | 60 |  |  |
| Linagliptin with metformin | Tablet containing 2.5 mg linagliptin with 850 mg metformin hydrochloride | Oral | Trajentamet | BY | MP NP | C15288 | P15288 | 120 | 5 |  | 60 |  |  |

1. Schedule 1, Part 1, after entry for Medroxyprogesterone in the form Injection containing medroxyprogesterone acetate 150 mg in 1 mL *[Brand: Depo-Ralovera]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Medroxyprogesterone | Injection containing medroxyprogesterone acetate 150 mg in 1 mL pre-filled syringe | Injection | Depo-Provera | PF | MP NP |  |  | 1 | 1 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Methotrexate in the form Tablet 2.5 mg
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Methotrexate | Tablet 2.5 mg | Oral | ARX-Methotrexate | XT | MP NP |  |  | 30 | 5 |  | 30 |  |  |

1. Schedule 1, Part 1, entry for Methotrexate in the form Tablet 10 mg
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Methotrexate | Tablet 10 mg | Oral | ARX-Methotrexate | XT | MP NP |  |  | 15 | 3 |  | 15 |  |  |
| Methotrexate | Tablet 10 mg | Oral | ARX-Methotrexate | XT | MP NP |  | P5648 | 50 | 2 |  | 50 |  |  |

1. Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Mycophenolic acid | Tablet containing mycophenolate mofetil 500 mg | Oral | Noumed Mycophenolate | VO | MP |  |  | 150 | 5 |  | 50 |  |  |
| Mycophenolic acid | Tablet containing mycophenolate mofetil 500 mg | Oral | Noumed Mycophenolate | VO | MP |  | P14238 | 300 | 5 |  | 50 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Naltrexone | Tablet containing naltrexone hydrochloride 50 mg | Oral | ARX-NALTREXONE | XT | MP NP | C13967 |  | 30 | 1 |  | 30 |  |  |

1. Schedule 1, Part 1, entry for Nebivolol in the form Tablet 1.25 mg (as hydrochloride)
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Nebivolol | Tablet 1.25 mg (as hydrochloride) | Oral | Nebivolol Viatris | AL | MP NP | C5324 | P5324 | 56 | 5 |  | 28 |  |  |
| Nebivolol | Tablet 1.25 mg (as hydrochloride) | Oral | Nebivolol Viatris | AL | MP NP | C14251 | P14251 | 112 | 5 |  | 28 |  |  |

1. Schedule 1, Part 1, entry for Nebivolol in the form Tablet 10 mg (as hydrochloride)
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Nebivolol | Tablet 10 mg (as hydrochloride) | Oral | Nebivolol Viatris | AL | MP NP | C5324 | P5324 | 28 | 5 |  | 28 |  |  |
| Nebivolol | Tablet 10 mg (as hydrochloride) | Oral | Nebivolol Viatris | AL | MP NP | C14251 | P14251 | 56 | 5 |  | 28 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Nivolumab | Injection concentrate for I.V. infusion 40 mg in 4 mL | Injection | Opdivo | BQ | MP | C14830 | P14830 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Nivolumab | Injection concentrate for I.V. infusion 40 mg in 4 mL | Injection | Opdivo | BQ | MP | C14001 | P14001 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Nivolumab | Injection concentrate for I.V. infusion 40 mg in 4 mL | Injection | Opdivo | BQ | MP | C11985 | P11985 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Nivolumab | Injection concentrate for I.V. infusion 40 mg in 4 mL | Injection | Opdivo | BQ | MP | C11468 C13433 | P11468 P13433 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Nivolumab | Injection concentrate for I.V. infusion 40 mg in 4 mL | Injection | Opdivo | BQ | MP | C10119 C10120 C13900 | P10119 P10120 P13900 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Nivolumab | Injection concentrate for I.V. infusion 40 mg in 4 mL | Injection | Opdivo | BQ | MP | C9216 C9312 C13445 C14816 | P9216 P9312 P13445 P14816 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Nivolumab | Injection concentrate for I.V. infusion 40 mg in 4 mL | Injection | Opdivo | BQ | MP | C9252 C9298 C9299 C9321 C11477 C13839 | P9252 P9298 P9299 P9321 P11477 P13839 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Nivolumab | Injection concentrate for I.V. infusion 40 mg in 4 mL | Injection | Opdivo | BQ | MP | C14676 | P14676 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Nivolumab | Injection concentrate for I.V. infusion 100 mg in 10 mL | Injection | Opdivo | BQ | MP | C14830 | P14830 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Nivolumab | Injection concentrate for I.V. infusion 100 mg in 10 mL | Injection | Opdivo | BQ | MP | C14001 | P14001 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Nivolumab | Injection concentrate for I.V. infusion 100 mg in 10 mL | Injection | Opdivo | BQ | MP | C11985 | P11985 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Nivolumab | Injection concentrate for I.V. infusion 100 mg in 10 mL | Injection | Opdivo | BQ | MP | C11468 C13433 | P11468 P13433 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Nivolumab | Injection concentrate for I.V. infusion 100 mg in 10 mL | Injection | Opdivo | BQ | MP | C10119 C10120 C13900 | P10119 P10120 P13900 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Nivolumab | Injection concentrate for I.V. infusion 100 mg in 10 mL | Injection | Opdivo | BQ | MP | C9216 C9312 C13445 C14816 | P9216 P9312 P13445 P14816 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Nivolumab | Injection concentrate for I.V. infusion 100 mg in 10 mL | Injection | Opdivo | BQ | MP | C9252 C9298 C9299 C9321 C11477 C13839 | P9252 P9298 P9299 P9321 P11477 P13839 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Nivolumab | Injection concentrate for I.V. infusion 100 mg in 10 mL | Injection | Opdivo | BQ | MP | C14676 | P14676 | See Note 3 | See Note 3 |  | 1 |  | D(100) |

1. Schedule 1, Part 1, entry for Olanzapine in the form Tablet 10 mg
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Olanzapine | Tablet 10 mg | Oral | APO-OLANZAPINE | TX | MP NP | C5856 C5869 |  | 28 | 5 |  | 28 |  |  |

1. Schedule 1, Part 1, entry for Onasemnogene abeparvovec
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Onasemnogene abeparvovec | Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 3 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 4 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 5 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 6 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 7 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 8 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 3 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 4 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 5 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 6 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 7 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 3 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 4 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 5 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 6 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 7 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 8 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Onasemnogene abeparvovec | Pack containing 9 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL | Injection | Zolgensma | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ondansetron | Syrup 4 mg (as hydrochloride dihydrate) per 5 mL, 50 mL | Oral | Zofran syrup 50 mL | AS | MP NP | C5721 | P5721 | 1 | 0 | V5721 | 1 |  |  |
| Ondansetron | Syrup 4 mg (as hydrochloride dihydrate) per 5 mL, 50 mL | Oral | Zofran syrup 50 mL | AS | MP | C5778 | P5778 | 1 | 0 | V5778 | 1 |  | C(100) |
| Ondansetron | Syrup 4 mg (as hydrochloride dihydrate) per 5 mL, 50 mL | Oral | Zofran syrup 50 mL | AS | MP NP | C15193 | P15193 | 1 | 1 |  | 1 |  |  |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | APO-Ondansetron | TX | MP NP | C4118 | P4118 | 4 | 0 | V4118 | 4 |  |  |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | APO-Ondansetron | TX | MP | C5778 | P5778 | 4 | 0 | V5778 | 4 |  | C(100) |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | APO-Ondansetron | TX | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | APX-Ondansetron | TY | MP NP | C4118 | P4118 | 4 | 0 | V4118 | 4 |  |  |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | APX-Ondansetron | TY | MP | C5778 | P5778 | 4 | 0 | V5778 | 4 |  | C(100) |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | APX-Ondansetron | TY | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | Ondansetron Mylan Tablets | AF | MP NP | C4118 | P4118 | 4 | 0 | V4118 | 4 |  |  |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | Ondansetron Mylan Tablets | AF | MP | C5778 | P5778 | 4 | 0 | V5778 | 4 |  | C(100) |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | Ondansetron Mylan Tablets | AF | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | Ondansetron SZ | HX | MP NP | C4118 | P4118 | 4 | 0 | V4118 | 4 |  |  |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | Ondansetron SZ | HX | MP | C5778 | P5778 | 4 | 0 | V5778 | 4 |  | C(100) |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | Ondansetron SZ | HX | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | Ondansetron Tablets Viatris | AL | MP NP | C4118 | P4118 | 4 | 0 | V4118 | 4 |  |  |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | Ondansetron Tablets Viatris | AL | MP | C5778 | P5778 | 4 | 0 | V5778 | 4 |  | C(100) |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | Ondansetron Tablets Viatris | AL | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | Ondansetron-DRLA | RZ | MP NP | C4118 | P4118 | 4 | 0 | V4118 | 4 |  |  |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | Ondansetron-DRLA | RZ | MP | C5778 | P5778 | 4 | 0 | V5778 | 4 |  | C(100) |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | Ondansetron-DRLA | RZ | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | Zofran | AS | MP NP | C4118 | P4118 | 4 | 0 | V4118 | 4 |  |  |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | Zofran | AS | MP | C5778 | P5778 | 4 | 0 | V5778 | 4 |  | C(100) |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | Zofran | AS | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | Zotren 4 | RF | MP NP | C4118 | P4118 | 4 | 0 | V4118 | 4 |  |  |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | Zotren 4 | RF | MP | C5778 | P5778 | 4 | 0 | V5778 | 4 |  | C(100) |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) | Oral | Zotren 4 | RF | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet (orally disintegrating) 4 mg | Oral | APX-Ondansetron ODT | TY | MP NP | C5618 | P5618 | 4 | 0 | V5618 | 4 |  |  |
| Ondansetron | Tablet (orally disintegrating) 4 mg | Oral | APX-Ondansetron ODT | TY | MP | C5743 | P5743 | 4 | 0 | V5743 | 4 |  | C(100) |
| Ondansetron | Tablet (orally disintegrating) 4 mg | Oral | APX-Ondansetron ODT | TY | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet (orally disintegrating) 4 mg | Oral | Ondansetron Mylan ODT | AF | MP NP | C5618 | P5618 | 4 | 0 | V5618 | 4 |  |  |
| Ondansetron | Tablet (orally disintegrating) 4 mg | Oral | Ondansetron Mylan ODT | AF | MP | C5743 | P5743 | 4 | 0 | V5743 | 4 |  | C(100) |
| Ondansetron | Tablet (orally disintegrating) 4 mg | Oral | Ondansetron Mylan ODT | AF | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet (orally disintegrating) 4 mg | Oral | Ondansetron ODT-DRLA | RZ | MP NP | C5618 | P5618 | 4 | 0 | V5618 | 4 |  |  |
| Ondansetron | Tablet (orally disintegrating) 4 mg | Oral | Ondansetron ODT-DRLA | RZ | MP | C5743 | P5743 | 4 | 0 | V5743 | 4 |  | C(100) |
| Ondansetron | Tablet (orally disintegrating) 4 mg | Oral | Ondansetron ODT-DRLA | RZ | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet (orally disintegrating) 4 mg | Oral | Ondansetron ODT Lupin | HQ | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet (orally disintegrating) 4 mg | Oral | Ondansetron SZ ODT | HX | MP NP | C5618 | P5618 | 4 | 0 | V5618 | 4 |  |  |
| Ondansetron | Tablet (orally disintegrating) 4 mg | Oral | Ondansetron SZ ODT | HX | MP | C5743 | P5743 | 4 | 0 | V5743 | 4 |  | C(100) |
| Ondansetron | Tablet (orally disintegrating) 4 mg | Oral | Ondansetron SZ ODT | HX | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet (orally disintegrating) 4 mg | Oral | Zotren ODT | RF | MP NP | C5618 | P5618 | 4 | 0 | V5618 | 4 |  |  |
| Ondansetron | Tablet (orally disintegrating) 4 mg | Oral | Zotren ODT | RF | MP | C5743 | P5743 | 4 | 0 | V5743 | 4 |  | C(100) |
| Ondansetron | Tablet (orally disintegrating) 4 mg | Oral | Zotren ODT | RF | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | APO-Ondansetron | TX | MP NP | C4118 | P4118 | 4 | 0 | V4118 | 4 |  |  |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | APO-Ondansetron | TX | MP | C5778 | P5778 | 4 | 0 | V5778 | 4 |  | C(100) |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | APO-Ondansetron | TX | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | APX-Ondansetron | TY | MP NP | C4118 | P4118 | 4 | 0 | V4118 | 4 |  |  |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | APX-Ondansetron | TY | MP | C5778 | P5778 | 4 | 0 | V5778 | 4 |  | C(100) |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | APX-Ondansetron | TY | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | Ondansetron Mylan Tablets | AF | MP NP | C4118 | P4118 | 4 | 0 | V4118 | 4 |  |  |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | Ondansetron Mylan Tablets | AF | MP | C5778 | P5778 | 4 | 0 | V5778 | 4 |  | C(100) |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | Ondansetron Mylan Tablets | AF | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | Ondansetron SZ | HX | MP NP | C4118 | P4118 | 4 | 0 | V4118 | 4 |  |  |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | Ondansetron SZ | HX | MP | C5778 | P5778 | 4 | 0 | V5778 | 4 |  | C(100) |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | Ondansetron SZ | HX | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | Ondansetron Tablets Viatris | AL | MP NP | C4118 | P4118 | 4 | 0 | V4118 | 4 |  |  |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | Ondansetron Tablets Viatris | AL | MP | C5778 | P5778 | 4 | 0 | V5778 | 4 |  | C(100) |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | Ondansetron Tablets Viatris | AL | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | Ondansetron-DRLA | RZ | MP NP | C4118 | P4118 | 4 | 0 | V4118 | 4 |  |  |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | Ondansetron-DRLA | RZ | MP | C5778 | P5778 | 4 | 0 | V5778 | 4 |  | C(100) |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | Ondansetron-DRLA | RZ | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | Zofran | AS | MP NP | C4118 | P4118 | 4 | 0 | V4118 | 4 |  |  |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | Zofran | AS | MP | C5778 | P5778 | 4 | 0 | V5778 | 4 |  | C(100) |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | Zofran | AS | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | Zotren 8 | RF | MP NP | C4118 | P4118 | 4 | 0 | V4118 | 4 |  |  |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | Zotren 8 | RF | MP | C5778 | P5778 | 4 | 0 | V5778 | 4 |  | C(100) |
| Ondansetron | Tablet 8 mg (as hydrochloride dihydrate) | Oral | Zotren 8 | RF | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet (orally disintegrating) 8 mg | Oral | APX-Ondansetron ODT | TY | MP NP | C5618 | P5618 | 4 | 0 | V5618 | 4 |  |  |
| Ondansetron | Tablet (orally disintegrating) 8 mg | Oral | APX-Ondansetron ODT | TY | MP | C5743 | P5743 | 4 | 0 | V5743 | 4 |  | C(100) |
| Ondansetron | Tablet (orally disintegrating) 8 mg | Oral | APX-Ondansetron ODT | TY | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet (orally disintegrating) 8 mg | Oral | Ondansetron Mylan ODT | AF | MP NP | C5618 | P5618 | 4 | 0 | V5618 | 4 |  |  |
| Ondansetron | Tablet (orally disintegrating) 8 mg | Oral | Ondansetron Mylan ODT | AF | MP | C5743 | P5743 | 4 | 0 | V5743 | 4 |  | C(100) |
| Ondansetron | Tablet (orally disintegrating) 8 mg | Oral | Ondansetron Mylan ODT | AF | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet (orally disintegrating) 8 mg | Oral | Ondansetron ODT Viatris | AL | MP NP | C5618 | P5618 | 4 | 0 | V5618 | 4 |  |  |
| Ondansetron | Tablet (orally disintegrating) 8 mg | Oral | Ondansetron ODT Viatris | AL | MP | C5743 | P5743 | 4 | 0 | V5743 | 4 |  | C(100) |
| Ondansetron | Tablet (orally disintegrating) 8 mg | Oral | Ondansetron ODT Viatris | AL | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet (orally disintegrating) 8 mg | Oral | Ondansetron ODT-DRLA | RZ | MP NP | C5618 | P5618 | 4 | 0 | V5618 | 4 |  |  |
| Ondansetron | Tablet (orally disintegrating) 8 mg | Oral | Ondansetron ODT-DRLA | RZ | MP | C5743 | P5743 | 4 | 0 | V5743 | 4 |  | C(100) |
| Ondansetron | Tablet (orally disintegrating) 8 mg | Oral | Ondansetron ODT-DRLA | RZ | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet (orally disintegrating) 8 mg | Oral | Ondansetron ODT Lupin | HQ | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet (orally disintegrating) 8 mg | Oral | Ondansetron SZ ODT | HX | MP NP | C5618 | P5618 | 4 | 0 | V5618 | 4 |  |  |
| Ondansetron | Tablet (orally disintegrating) 8 mg | Oral | Ondansetron SZ ODT | HX | MP | C5743 | P5743 | 4 | 0 | V5743 | 4 |  | C(100) |
| Ondansetron | Tablet (orally disintegrating) 8 mg | Oral | Ondansetron SZ ODT | HX | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Tablet (orally disintegrating) 8 mg | Oral | Zotren ODT | RF | MP NP | C5618 | P5618 | 4 | 0 | V5618 | 4 |  |  |
| Ondansetron | Tablet (orally disintegrating) 8 mg | Oral | Zotren ODT | RF | MP | C5743 | P5743 | 4 | 0 | V5743 | 4 |  | C(100) |
| Ondansetron | Tablet (orally disintegrating) 8 mg | Oral | Zotren ODT | RF | MP NP | C15193 | P15193 | 10 | 1 |  | 10 |  |  |
| Ondansetron | Wafer 4 mg | Oral | Zofran Zydis | AS | MP NP | C15193 |  | 10 | 1 |  | 10 |  |  |
| Ondansetron | Wafer 8 mg | Oral | Zofran Zydis | AS | MP NP | C15193 |  | 10 | 1 |  | 10 |  |  |

1. Schedule 1, Part 1, entry for Osimertinib in the form Tablet 40 mg

*omit from the column headed “Circumstances”:* C11181 C11183 *substitute:* C15257 C15283 C15310

1. Schedule 1, Part 1, entry for Osimertinib in the form Tablet 80 mg

*omit from the column headed “Circumstances”:* C11178 C11181 C11183 C11185 *substitute:* C15257 C15281 C15283 C15299 C15329

1. Schedule 1, Part 1, entry for Ozanimod in the form Capsule 920 micrograms *[Maximum Quantity: 28; Number of Repeats: 5]*
2. *omit from the column headed “Circumstances”:* C13993
3. *omit from the column headed “Purposes”:* P13993
4. Schedule 1, Part 1, entry for Pembrolizumab
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pembrolizumab | Solution concentrate for I.V. infusion 100 mg in 4 mL | Injection | Keytruda | MK | MP | C14818 | P14818 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Pembrolizumab | Solution concentrate for I.V. infusion 100 mg in 4 mL | Injection | Keytruda | MK | MP | C13431 C13432 | P13431 P13432 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Pembrolizumab | Solution concentrate for I.V. infusion 100 mg in 4 mL | Injection | Keytruda | MK | MP | C10705 C14770 C14786 | P10705 P14770 P14786 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Pembrolizumab | Solution concentrate for I.V. infusion 100 mg in 4 mL | Injection | Keytruda | MK | MP | C14817 | P14817 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Pembrolizumab | Solution concentrate for I.V. infusion 100 mg in 4 mL | Injection | Keytruda | MK | MP | C10676 C10688 C10701 C13436 C13437 | P10676 P10688 P10701 P13436 P13437 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Pembrolizumab | Solution concentrate for I.V. infusion 100 mg in 4 mL | Injection | Keytruda | MK | MP | C13726 C13727 C13728 C13730 C13731 C13732 C13735 C13736 C13739 C13741 C13948 C13949 C14027 C14028 C14044 C14324 C14403 C14404 C14405 | P13726 P13727 P13728 P13730 P13731 P13732 P13735 P13736 P13739 P13741 P13948 P13949 P14027 P14028 P14044 P14324 P14403 P14404 P14405 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Pembrolizumab | Solution concentrate for I.V. infusion 100 mg in 4 mL | Injection | Keytruda | MK | MP | C14727 | P14727 | See Note 3 | See Note 3 |  | 1 |  | D(100) |

1. Schedule 1, Part 1, entry for Perindopril in the form Tablet containing perindopril arginine 2.5 mg
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Perindopril | Tablet containing perindopril arginine 2.5 mg | Oral | Perindopril Arginine Sandoz | SZ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Perindopril | Tablet containing perindopril arginine 2.5 mg | Oral | Perindopril Arginine Sandoz | SZ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

1. Schedule 1, Part 1, entry for Perindopril in the form Tablet containing perindopril arginine 5 mg
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Perindopril | Tablet containing perindopril arginine 5 mg | Oral | Perindopril Arginine Sandoz | SZ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Perindopril | Tablet containing perindopril arginine 5 mg | Oral | Perindopril Arginine Sandoz | SZ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

1. Schedule 1, Part 1, entry for Perindopril in the form Tablet containing perindopril arginine 10 mg
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Perindopril | Tablet containing perindopril arginine 10 mg | Oral | Perindopril Arginine Sandoz | SZ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Perindopril | Tablet containing perindopril arginine 10 mg | Oral | Perindopril Arginine Sandoz | SZ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pioglitazone | Tablet 15 mg (as hydrochloride) | Oral | Acpio 15 | RF | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 15 mg (as hydrochloride) | Oral | Acpio 15 | RF | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 15 mg (as hydrochloride) | Oral | Actaze | RW | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 15 mg (as hydrochloride) | Oral | Actaze | RW | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 15 mg (as hydrochloride) | Oral | Actos | EW | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 15 mg (as hydrochloride) | Oral | Actos | EW | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 15 mg (as hydrochloride) | Oral | APOTEX-Pioglitazone | TX | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 15 mg (as hydrochloride) | Oral | APOTEX-Pioglitazone | TX | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 15 mg (as hydrochloride) | Oral | Vexazone | AF | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 15 mg (as hydrochloride) | Oral | Vexazone | AF | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 30 mg (as hydrochloride) | Oral | Acpio 30 | RF | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 30 mg (as hydrochloride) | Oral | Acpio 30 | RF | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 30 mg (as hydrochloride) | Oral | Actaze | RW | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 30 mg (as hydrochloride) | Oral | Actaze | RW | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 30 mg (as hydrochloride) | Oral | Actos | EW | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 30 mg (as hydrochloride) | Oral | Actos | EW | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 30 mg (as hydrochloride) | Oral | APOTEX-Pioglitazone | TX | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 30 mg (as hydrochloride) | Oral | APOTEX-Pioglitazone | TX | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 30 mg (as hydrochloride) | Oral | Vexazone | AF | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 30 mg (as hydrochloride) | Oral | Vexazone | AF | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 45 mg (as hydrochloride) | Oral | Acpio 45 | RF | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 45 mg (as hydrochloride) | Oral | Acpio 45 | RF | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 45 mg (as hydrochloride) | Oral | Actaze | RW | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 45 mg (as hydrochloride) | Oral | Actaze | RW | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 45 mg (as hydrochloride) | Oral | Actos | EW | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 45 mg (as hydrochloride) | Oral | Actos | EW | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 45 mg (as hydrochloride) | Oral | APOTEX-Pioglitazone | TX | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 45 mg (as hydrochloride) | Oral | APOTEX-Pioglitazone | TX | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 45 mg (as hydrochloride) | Oral | Vexazone | AF | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 45 mg (as hydrochloride) | Oral | Vexazone | AF | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |

1. Schedule 1, Part 1, entry for Plerixafor
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Plerixafor | Injection 24 mg in 1.2 mL | Injection | PLERIXAFOR EUGIA | YG | MP | C4549 C9329 |  | 1 | 1 |  | 1 |  | D(100) |

1. Schedule 1, Part 1, entry for Quetiapine in the form Tablet (modified release) 50 mg (as fumarate)
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Quetiapine | Tablet (modified release) 50 mg (as fumarate) | Oral | Quetiapine Sandoz XR | SZ | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |

1. Schedule 1, Part 1, entry for Quetiapine in the form Tablet (modified release) 150 mg (as fumarate)
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Quetiapine | Tablet (modified release) 150 mg (as fumarate) | Oral | Quetiapine Sandoz XR | SZ | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |

1. Schedule 1, Part 1, entry for Quetiapine in the form Tablet (modified release) 200 mg (as fumarate)
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Quetiapine | Tablet (modified release) 200 mg (as fumarate) | Oral | Quetiapine Sandoz XR | SZ | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |

1. Schedule 1, Part 1, entry for Quetiapine in the form Tablet (modified release) 300 mg (as fumarate)
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Quetiapine | Tablet (modified release) 300 mg (as fumarate) | Oral | Quetiapine Sandoz XR | SZ | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |

1. Schedule 1, Part 1, entry for Quetiapine in the form Tablet (modified release) 400 mg (as fumarate)
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Quetiapine | Tablet (modified release) 400 mg (as fumarate) | Oral | Quetiapine Sandoz XR | SZ | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |

1. Schedule 1, Part 1, entry for Ramipril in the form Tablet 2.5 mg
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ramipril | Tablet 2.5 mg | Oral | Ramipril Viatris | AL | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ramipril | Tablet 2.5 mg | Oral | Ramipril Viatris | AL | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

1. Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 5 mg (as calcium)
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Rosuvastatin | Tablet 5 mg (as calcium) | Oral | Noumed Rosuvastatin | VO | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Rosuvastatin | Tablet 5 mg (as calcium) | Oral | Noumed Rosuvastatin | VO | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

1. Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 10 mg (as calcium)
2. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Rosuvastatin | Tablet 10 mg (as calcium) | Oral | APO-ROSUVASTATIN | TX | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Rosuvastatin | Tablet 10 mg (as calcium) | Oral | APO-ROSUVASTATIN | TX | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Rosuvastatin | Tablet 10 mg (as calcium) | Oral | Noumed Rosuvastatin | VO | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Rosuvastatin | Tablet 10 mg (as calcium) | Oral | Noumed Rosuvastatin | VO | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Rosuvastatin | Tablet 20 mg (as calcium) | Oral | Noumed Rosuvastatin | VO | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Rosuvastatin | Tablet 20 mg (as calcium) | Oral | Noumed Rosuvastatin | VO | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

1. Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 40 mg (as calcium)
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Rosuvastatin | Tablet 40 mg (as calcium) | Oral | Noumed Rosuvastatin | VO | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Rosuvastatin | Tablet 40 mg (as calcium) | Oral | Noumed Rosuvastatin | VO | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ruxolitinib | Tablet 5 mg | Oral | Jakavi | NV | MP | C13907 C13911 | P13907 P13911 | 56 | 0 |  | 56 |  | C(100) |
| Ruxolitinib | Tablet 5 mg | Oral | Jakavi | NV | MP | C13867 C13906 | P13867 P13906 | 56 | 5 |  | 56 |  |  |
| Ruxolitinib | Tablet 5 mg | Oral | Jakavi | NV | MP | C13876 C13892 | P13876 P13892 | 56 | 5 |  | 56 |  | C(100) |
| Ruxolitinib | Tablet 5 mg | Oral | Jakavi | NV | MP | C13127 C13173 | P13127 P13173 | 112 | 0 |  | 56 |  |  |
| Ruxolitinib | Tablet 5 mg | Oral | Jakavi | NV | MP | C13128 C13130 | P13128 P13130 | 112 | 5 |  | 56 |  |  |
| Ruxolitinib | Tablet 10 mg | Oral | Jakavi | NV | MP | C13127 C13173 | P13127 P13173 | 56 | 0 |  | 56 |  |  |
| Ruxolitinib | Tablet 10 mg | Oral | Jakavi | NV | MP | C13907 C13911 | P13907 P13911 | 56 | 0 |  | 56 |  | C(100) |
| Ruxolitinib | Tablet 10 mg | Oral | Jakavi | NV | MP | C13128 C13130 C13867 C13906 | P13128 P13130 P13867 P13906 | 56 | 5 |  | 56 |  |  |
| Ruxolitinib | Tablet 10 mg | Oral | Jakavi | NV | MP | C13876 C13892 | P13876 P13892 | 56 | 5 |  | 56 |  | C(100) |
| Ruxolitinib | Tablet 15 mg | Oral | Jakavi | NV | MP | C13127 C13173 | P13127 P13173 | 56 | 0 |  | 56 |  |  |
| Ruxolitinib | Tablet 15 mg | Oral | Jakavi | NV | MP | C13128 C13130 | P13128 P13130 | 56 | 5 |  | 56 |  |  |
| Ruxolitinib | Tablet 20 mg | Oral | Jakavi | NV | MP | C13127 C13173 | P13127 P13173 | 56 | 0 |  | 56 |  |  |
| Ruxolitinib | Tablet 20 mg | Oral | Jakavi | NV | MP | C13128 C13130 | P13128 P13130 | 56 | 5 |  | 56 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Saxagliptin | Tablet 2.5 mg (as hydrochloride) | Oral | Onglyza | AP | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Saxagliptin | Tablet 2.5 mg (as hydrochloride) | Oral | Onglyza | AP | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |
| Saxagliptin | Tablet 5 mg (as hydrochloride) | Oral | Onglyza | AP | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Saxagliptin | Tablet 5 mg (as hydrochloride) | Oral | Onglyza | AP | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |

1. Schedule 1, Part 1, entry for Saxagliptin with dapagliflozin
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Saxagliptin with dapagliflozin | Tablet containing saxagliptin 5 mg with dapaglifozin 10 mg | Oral | Qtern 5/10 | AP | MP | C15269 | P15269 | 28 | 5 |  | 28 |  |  |
| Saxagliptin with dapagliflozin | Tablet containing saxagliptin 5 mg with dapaglifozin 10 mg | Oral | Qtern 5/10 | AP | MP NP | C15270 | P15270 | 56 | 5 |  | 28 |  |  |

1. Schedule 1, Part 1, entry for Saxagliptin with metformin
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Saxagliptin with metformin | Tablet (modified release) containing 2.5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride | Oral | Kombiglyze XR 2.5/1000 | AP | MP NP | C15276 | P15276 | 56 | 5 |  | 56 |  |  |
| Saxagliptin with metformin | Tablet (modified release) containing 2.5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride | Oral | Kombiglyze XR 2.5/1000 | AP | MP NP | C15288 | P15288 | 112 | 5 |  | 56 |  |  |
| Saxagliptin with metformin | Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride | Oral | Kombiglyze XR 5/1000 | AP | MP NP | C15276 | P15276 | 28 | 5 |  | 28 |  |  |
| Saxagliptin with metformin | Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride | Oral | Kombiglyze XR 5/1000 | AP | MP NP | C15288 | P15288 | 56 | 5 |  | 28 |  |  |
| Saxagliptin with metformin | Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 500 mg metformin hydrochloride | Oral | Kombiglyze XR 5/500 | AP | MP NP | C15276 | P15276 | 28 | 5 |  | 28 |  |  |
| Saxagliptin with metformin | Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 500 mg metformin hydrochloride | Oral | Kombiglyze XR 5/500 | AP | MP NP | C15288 | P15288 | 56 | 5 |  | 28 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Secukinumab | Injection 150 mg in 1 mL pre-filled pen | Injection | Cosentyx | NV | MP | C11390 C12392 | P11390 P12392 | 1 | 0 |  | 1 |  |  |
| Secukinumab | Injection 150 mg in 1 mL pre-filled pen | Injection | Cosentyx | NV | MP | C9064 C9429 | P9064 P9429 | 1 | 2 |  | 1 |  |  |
| Secukinumab | Injection 150 mg in 1 mL pre-filled pen | Injection | Cosentyx | NV | MP | C9063 C9105 C9431 C10431 C14692 | P9063 P9105 P9431 P10431 P14692 | 1 | 5 |  | 1 |  |  |
| Secukinumab | Injection 150 mg in 1 mL pre-filled pen | Injection | Cosentyx | NV | MP | C8831 C9064 | P8831 P9064 | 2 | 2 |  | 2 |  |  |
| Secukinumab | Injection 150 mg in 1 mL pre-filled pen | Injection | Cosentyx | NV | MP | C15279 C15295 C15316 C15328 | P15279 P15295 P15316 P15328 | 2 | 3 |  | 2 |  |  |
| Secukinumab | Injection 150 mg in 1 mL pre-filled pen | Injection | Cosentyx | NV | MP | C6696 C8830 C8892 C9063 C9105 C15317 C15325 | P6696 P8830 P8892 P9063 P9105 P15317 P15325 | 2 | 5 |  | 2 |  |  |
| Secukinumab | Injection 150 mg in 1 mL pre-filled pen | Injection | Cosentyx | NV | MP | C9069 C9078 C9155 C14655 C14662 C14670 | P9069 P9078 P9155 P14655 P14662 P14670 | 4 | 0 |  | 1 |  |  |
| Secukinumab | Injection 150 mg in 1 mL pre-filled pen | Injection | Cosentyx | NV | MP | C15127 C15137 C15158 | P15127 P15137 P15158 | 5 | 0 |  | 1 |  |  |
| Secukinumab | Injection 150 mg in 1 mL pre-filled pen | Injection | Cosentyx | NV | MP | C9069 C9078 C9155 C11089 C11096 C11138 C11154 C14430 C14462 C15280 C15296 C15307 | P9069 P9078 P9155 P11089 P11096 P11138 P11154 P14430 P14462 P15280 P15296 P15307 | 8 | 0 |  | 2 |  |  |

1. Schedule 1, Part 1, entry for Semaglutide in each of the forms: Solution for injection 2 mg in 1.5 mL pre-filled pen; and Solution for injection 4 mg in 3 mL pre-filled pen

*omit from the column headed “Circumstances”:* **C5469 C5478 C5500** *substitute:* **C15263 C15301**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sitagliptin | Tablet 25 mg | Oral | Januvia | XW | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 25 mg | Oral | Januvia | XW | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 25 mg | Oral | Sitagliptin Lupin | GQ | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 25 mg | Oral | Sitagliptin Lupin | GQ | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 25 mg | Oral | Sitagliptin Sandoz Pharma | SZ | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 25 mg | Oral | Sitagliptin Sandoz Pharma | SZ | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 25 mg | Oral | Sitagliptin SUN | RA | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 25 mg | Oral | Sitagliptin SUN | RA | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 25 mg | Oral | Sitaglo | CR | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 25 mg | Oral | Sitaglo | CR | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 25 mg | Oral | Xelevia | XT | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 25 mg | Oral | Xelevia | XT | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 50 mg | Oral | Januvia | XW | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 50 mg | Oral | Januvia | XW | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 50 mg | Oral | Sitagliptin Lupin | GQ | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 50 mg | Oral | Sitagliptin Lupin | GQ | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 50 mg | Oral | Sitagliptin Sandoz Pharma | SZ | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 50 mg | Oral | Sitagliptin Sandoz Pharma | SZ | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 50 mg | Oral | Sitagliptin SUN | RA | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 50 mg | Oral | Sitagliptin SUN | RA | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 50 mg | Oral | Sitaglo | CR | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 50 mg | Oral | Sitaglo | CR | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 50 mg | Oral | Xelevia | XT | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 50 mg | Oral | Xelevia | XT | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 100 mg | Oral | Januvia | XW | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 100 mg | Oral | Januvia | XW | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 100 mg | Oral | Sitagliptin Lupin | GQ | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 100 mg | Oral | Sitagliptin Lupin | GQ | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 100 mg | Oral | Sitagliptin Sandoz Pharma | SZ | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 100 mg | Oral | Sitagliptin Sandoz Pharma | SZ | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 100 mg | Oral | Sitagliptin SUN | RA | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 100 mg | Oral | Sitagliptin SUN | RA | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 100 mg | Oral | Sitaglo | CR | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 100 mg | Oral | Sitaglo | CR | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 100 mg | Oral | Xelevia | XT | MP NP | C15261 | P15261 | 28 | 5 |  | 28 |  |  |
| Sitagliptin | Tablet 100 mg | Oral | Xelevia | XT | MP NP | C15287 | P15287 | 56 | 5 |  | 28 |  |  |

1. Schedule 1, Part 1, entry for Sitagliptin with metformin
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sitagliptin with metformin | Tablet (modified release) containing 50 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | Janumet XR | XW | MP NP | C15276 | P15276 | 56 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet (modified release) containing 50 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | Janumet XR | XW | MP NP | C15288 | P15288 | 112 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet (modified release) containing 50 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | Sitagliptin/Metformin Sandoz XR | SZ | MP NP | C15276 | P15276 | 56 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet (modified release) containing 50 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | Sitagliptin/Metformin Sandoz XR | SZ | MP NP | C15288 | P15288 | 112 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet (modified release) containing 100 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | Janumet XR | XW | MP NP | C15276 | P15276 | 28 | 5 |  | 28 |  |  |
| Sitagliptin with metformin | Tablet (modified release) containing 100 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | Janumet XR | XW | MP NP | C15288 | P15288 | 56 | 5 |  | 28 |  |  |
| Sitagliptin with metformin | Tablet (modified release) containing 100 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | Sitagliptin/Metformin Sandoz XR | SZ | MP NP | C15276 | P15276 | 28 | 5 |  | 28 |  |  |
| Sitagliptin with metformin | Tablet (modified release) containing 100 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | Sitagliptin/Metformin Sandoz XR | SZ | MP NP | C15288 | P15288 | 56 | 5 |  | 28 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | Janumet | XW | MP NP | C15276 | P15276 | 56 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | Janumet | XW | MP NP | C15288 | P15288 | 112 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | SITAGLIPTIN/METFORMIN 50/1000 SUN | RA | MP NP | C15276 | P15276 | 56 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | SITAGLIPTIN/METFORMIN 50/1000 SUN | RA | MP NP | C15288 | P15288 | 112 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | Sitagliptin/Metformin Sandoz | SZ | MP NP | C15276 | P15276 | 56 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | Sitagliptin/Metformin Sandoz | SZ | MP NP | C15288 | P15288 | 112 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | Velmetia | XT | MP NP | C15276 | P15276 | 56 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | Velmetia | XT | MP NP | C15288 | P15288 | 112 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride | Oral | Janumet | XW | MP NP | C15276 | P15276 | 56 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride | Oral | Janumet | XW | MP NP | C15288 | P15288 | 112 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride | Oral | SITAGLIPTIN/METFORMIN 50/500 SUN | RA | MP NP | C15276 | P15276 | 56 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride | Oral | SITAGLIPTIN/METFORMIN 50/500 SUN | RA | MP NP | C15288 | P15288 | 112 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride | Oral | Sitagliptin/Metformin Sandoz | SZ | MP NP | C15276 | P15276 | 56 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride | Oral | Sitagliptin/Metformin Sandoz | SZ | MP NP | C15288 | P15288 | 112 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride | Oral | Velmetia | XT | MP NP | C15276 | P15276 | 56 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride | Oral | Velmetia | XT | MP NP | C15288 | P15288 | 112 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride | Oral | Janumet | XW | MP NP | C15276 | P15276 | 56 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride | Oral | Janumet | XW | MP NP | C15288 | P15288 | 112 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride | Oral | SITAGLIPTIN/METFORMIN 50/850 SUN | RA | MP NP | C15276 | P15276 | 56 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride | Oral | SITAGLIPTIN/METFORMIN 50/850 SUN | RA | MP NP | C15288 | P15288 | 112 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride | Oral | Sitagliptin/Metformin Sandoz | SZ | MP NP | C15276 | P15276 | 56 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride | Oral | Sitagliptin/Metformin Sandoz | SZ | MP NP | C15288 | P15288 | 112 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride | Oral | Velmetia | XT | MP NP | C15276 | P15276 | 56 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride | Oral | Velmetia | XT | MP NP | C15288 | P15288 | 112 | 5 |  | 56 |  |  |

1. Schedule 1, Part 1, entry for Sumatriptan in the form Tablet 50 mg (as succinate)
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sumatriptan | Tablet 50 mg (as succinate) | Oral | IMIGRAN MIGRAINE | AS | MP NP | C5259 |  | 4 | 5 |  | 2 |  |  |

1. Schedule 1, Part 1, entry for Tafamidis
2. *omit from the column headed “Circumstances”:* **C15088**
3. *insert in numerical order in the column headed “Circumstances”:* **C15303**
4. Schedule 1, Part 1, entry for Tenofovir with emtricitabine

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Tenofovir with emtricitabine | Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg | Oral | CIPLA TENOFOVIR + EMTRICITABINE 300/200 | LR | MP NP | C11143 | P11143 | 30 | 2 |  | 30 |  |  |
| Tenofovir with emtricitabine | Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg | Oral | CIPLA TENOFOVIR + EMTRICITABINE 300/200 | LR | MP NP | C6985 C6986 | P6985 P6986 | 60 | 5 |  | 30 |  | C(100) |
| Tenofovir with emtricitabine | Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg | Oral | Tenofovir/Emtricitabine 300/200 APOTEX | TX | MP NP | C11143 | P11143 | 30 | 2 |  | 30 |  |  |
| Tenofovir with emtricitabine | Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg | Oral | Tenofovir/Emtricitabine 300/200 APOTEX | TX | MP NP | C6985 C6986 | P6985 P6986 | 60 | 5 |  | 30 |  | C(100) |
| Tenofovir with emtricitabine | Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg | Oral | TENOFOVIR/EMTRICITABINE 300/200 ARX | XT | MP NP | C11143 | P11143 | 30 | 2 |  | 30 |  |  |
| Tenofovir with emtricitabine | Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg | Oral | TENOFOVIR/EMTRICITABINE 300/200 ARX | XT | MP NP | C6985 C6986 | P6985 P6986 | 60 | 5 |  | 30 |  | C(100) |
| Tenofovir with emtricitabine | Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg | Oral | Tenofovir Disoproxil Emtricitabine Viatris 300/200 | AL | MP NP | C11143 | P11143 | 30 | 2 |  | 30 |  |  |
| Tenofovir with emtricitabine | Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg | Oral | Tenofovir Disoproxil Emtricitabine Viatris 300/200 | AL | MP NP | C6985 C6986 | P6985 P6986 | 60 | 5 |  | 30 |  | C(100) |
| Tenofovir with emtricitabine | Tablet containing tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg | Oral | Tenofovir EMT GH | GQ | MP NP | C11143 | P11143 | 30 | 2 |  | 30 |  |  |
| Tenofovir with emtricitabine | Tablet containing tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg | Oral | Tenofovir EMT GH | GQ | MP NP | C6985 C6986 | P6985 P6986 | 60 | 5 |  | 30 |  | C(100) |
| Tenofovir with emtricitabine | Tablet containing tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg | Oral | Tenofovir/Emtricitabine Sandoz 301/200 | SZ | MP NP | C11143 | P11143 | 30 | 2 |  | 30 |  |  |
| Tenofovir with emtricitabine | Tablet containing tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg | Oral | Tenofovir/Emtricitabine Sandoz 301/200 | SZ | MP NP | C6985 C6986 | P6985 P6986 | 60 | 5 |  | 30 |  | C(100) |

1. Schedule 1, Part 1, entry for Teriparatide in the form Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled cartridge *[Maximum Quantity: 2; Number of Repeats: 5]*

*omit from the column headed “Number of Repeats”:* 5 *substitute:* 2

1. Schedule 1, Part 1, entry for Testosterone in the form I.M. injection containing testosterone undecanoate 1,000 mg in 4 mL
   1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Testosterone | I.M. injection containing testosterone undecanoate 1,000 mg in 4 mL | Injection | Testosterone ADVZ 1000 | BZ | MP | C6324 C6910 C6919 C6933 C6934 |  | 1 | 1 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Tobramycin in the form Solution for inhalation 300 mg in 5 mL *[Brand: Tobramycin WKT]*

*omit from the column headed “Responsible Person” (all instances):* LI *substitute (all instances):* JU

1. Schedule 1, Part 1, entry for Upadacitinib in each of the forms: Tablet 15 mg; and Tablet 30 mg *[Maximum Quantity: 28; Number of Repeats: 5]*
2. *omit from the column headed “Circumstances”:* **C13930**
3. *omit from the column headed “Purposes”:* **P13930**
4. Schedule 1, Part 1, entry for Ustekinumab in the form Injection 90 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 1]*
5. *omit from the column headed “Circumstances”:* **C14009**
6. *omit from the column headed “Purposes”:* **P14009**
7. Schedule 1, Part 1, entry for Valaciclovir

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Valaciclovir | Tablet 500 mg (as hydrochloride) | Oral | NOUMED VALACICLOVIR | VO | MP NP | C5940 C5961 |  | 30 | 5 |  | 30 |  |  |

1. Schedule 1, Part 1, entry for Vildagliptin in the form Tablet 50 mg *[Maximum Quantity: 60; Number of Repeats: 5]*
2. *omit from the column headed “Circumstances”:* **C6346 C6363 C6376** *substitute:* **C15261**
3. *omit from the column headed “Purposes”:* **P6346 P6363 P6376** *substitute:* **P15261**
4. Schedule 1, Part 1, entry for Vildagliptin in the form Tablet 50 mg *[Maximum Quantity: 120; Number of Repeats: 5]*
5. *omit from the column headed “Circumstances”:* **C14978 C14999 C15000** *substitute:* **C15287**
6. *omit from the column headed “Purposes”:* **P14978 P14999 P15000** *substitute:* **P15287**
7. Schedule 1, Part 1, entry for Vildagliptin with metformin

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Vildagliptin with metformin | Tablet containing 50 mg vildagliptin with 1000 mg metformin hydrochloride | Oral | Galvumet 50/1000 | NV | MP NP | C15276 | P15276 | 60 | 5 |  | 60 |  |  |
| Vildagliptin with metformin | Tablet contaiing 50 mg vildagliptin with 1000 mg metformin hydrochloride | Oral | Galvumet 50/1000 | NV | MP NP | C15288 | P15288 | 120 | 5 |  | 60 |  |  |
| Vildagliptin with metformin | Tablet containing 50 mg vildagliptin with 500 mg metformin hydrochloride | Oral | Galvumet 50/500 | NV | MP NP | C15276 | P15276 | 60 | 5 |  | 60 |  |  |
| Vildagliptin with metformin | Tablet containing 50 mg vildagliptin with 500 mg metformin hydrochloride | Oral | Galvumet 50/500 | NV | MP NP | C15288 | P15288 | 120 | 5 |  | 60 |  |  |
| Vildagliptin with metformin | Tablet containing 50 mg vildagliptin with 850 mg metformin hydrochloride | Oral | Galvumet 50/850 | NV | MP NP | C15276 | P15276 | 60 | 5 |  | 60 |  |  |
| Vildagliptin with metformin | Tablet containing 50 mg vildagliptin with 850 mg metformin hydrochloride | Oral | Galvumet 50/850 | NV | MP NP | C15288 | P15288 | 120 | 5 |  | 60 |  |  |

1. Schedule 1, Part 1, entry for Vosoritide in each of the forms: Powder for injection 400 micrograms with diluent; Powder for injection 560 micrograms with diluent; and Powder for injection 1.2 mg with diluent

*omit from the column headed “Circumstances”:* **C13929**

1. Schedule 1, Part 2
   1. *insert as first entry:*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Bisacodyl | Enemas 10 mg in 5 mL, 25 | Rectal | Bisalax | OX | 1 |  |  |

1. Schedule 1, Part 2, omit entry for Insulin neutral with insulin isophane
2. Schedule 1, Part 2, after entry for Hypromellose with dextran
   1. *insert:*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Ketoconazole | Cream 20 mg per g, 30 g | Application | Nizoral 2% Cream | JT | 1 |  |  |

1. Schedule 1, Part 2, omit entry for Macrogol 3350
2. Schedule 1, Part 2, omit entry for Pancrelipase
3. Schedule 1, Part 2, omit entry for Paraffin with retinol palmitate
4. Schedule 1, Part 2, omit entry for Raltegravir
5. Schedule 3
   1. *omit:*

|  |  |  |
| --- | --- | --- |
| LI | Luminarie Pty Ltd | 18 601 868 375 |

1. Schedule 3, after details relevant for Responsible Person code XY
   1. *insert:*

|  |  |  |
| --- | --- | --- |
| YG | EUGIA PHARMA (AUSTRALIA) PTY LTD | 57 656 083 028 |

1. Schedule 3, after details relevant for Responsible Person code YN
   1. *insert:*

|  |  |  |
| --- | --- | --- |
| YO | The Trustee for ORSPEC PHARMA UNIT TRUST | 15 634 980 417 |

1. Schedule 4, Part 1, omit entry for Circumstances Code “C4072”
2. Schedule 4, Part 1, omit entry for Circumstances Code “C4274”
3. Schedule 4, Part 1, omit entry for Circumstances Code “C4275”
4. Schedule 4, Part 1, omit entry for Circumstances Code “C4349”
5. Schedule 4, Part 1, omit entry for Circumstances Code “C4363”
6. Schedule 4, Part 1, omit entry for Circumstances Code “C4364”
7. Schedule 4, Part 1, omit entry for Circumstances Code “C4388”
8. Schedule 4, Part 1, omit entry for Circumstances Code “C4423”
9. Schedule 4, Part 1, omit entry for Circumstances Code “C4427”
10. Schedule 4, Part 1, omit entry for Circumstances Code “C4991”
11. Schedule 4, Part 1, omit entry for Circumstances Code “C5469”
12. Schedule 4, Part 1, omit entry for Circumstances Code “C5478”
13. Schedule 4, Part 1, omit entry for Circumstances Code “C5500”
14. Schedule 4, Part 1, omit entry for Circumstances Code “C5629”
15. Schedule 4, Part 1, omit entry for Circumstances Code “C5631”
16. Schedule 4, Part 1, omit entry for Circumstances Code “C5657”
17. Schedule 4, Part 1, omit entry for Circumstances Code “C5739”
18. Schedule 4, Part 1, omit entry for Circumstances Code “C5779”
19. Schedule 4, Part 1, omit entry for Circumstances Code “C5798”
20. Schedule 4, Part 1, omit entry for Circumstances Code “C5953”
21. Schedule 4, Part 1, omit entry for Circumstances Code “C5966”
22. Schedule 4, Part 1, omit entry for Circumstances Code “C6333”
23. Schedule 4, Part 1, omit entry for Circumstances Code “C6334”
24. Schedule 4, Part 1, omit entry for Circumstances Code “C6335”
25. Schedule 4, Part 1, omit entry for Circumstances Code “C6336”
26. Schedule 4, Part 1, omit entry for Circumstances Code “C6344”
27. Schedule 4, Part 1, omit entry for Circumstances Code “C6346”
28. Schedule 4, Part 1, omit entry for Circumstances Code “C6357”
29. Schedule 4, Part 1, omit entry for Circumstances Code “C6363”
30. Schedule 4, Part 1, omit entry for Circumstances Code “C6376”
31. Schedule 4, Part 1, entry for Circumstances Code “C6434”

*omit from the column headed “Listed Drug”:* **Ketoconazole**

1. Schedule 4, Part 1, omit entry for Circumstances Code “C6443”
2. Schedule 4, Part 1, omit entry for Circumstances Code “C6645”
3. Schedule 4, Part 1, omit entry for Circumstances Code “C6664”
4. Schedule 4, Part 1, omit entry for Circumstances Code “C7492”
5. Schedule 4, Part 1, omit entry for Circumstances Code “C7495”
6. Schedule 4, Part 1, omit entry for Circumstances Code “C7498”
7. Schedule 4, Part 1, omit entry for Circumstances Code “C7505”
8. Schedule 4, Part 1, omit entry for Circumstances Code “C7506”
9. Schedule 4, Part 1, omit entry for Circumstances Code “C7507”
10. Schedule 4, Part 1, omit entry for Circumstances Code “C7524”
11. Schedule 4, Part 1, omit entry for Circumstances Code “C7528”
12. Schedule 4, Part 1, omit entry for Circumstances Code “C7530”
13. Schedule 4, Part 1, omit entry for Circumstances Code “C7541”
14. Schedule 4, Part 1, omit entry for Circumstances Code “C7556”
15. Schedule 4, Part 1, omit entry for Circumstances Code “C7598”
16. Schedule 4, Part 1, omit entry for Circumstances Code “C7629”
17. Schedule 4, Part 1, omit entry for Circumstances Code “C7645”
18. Schedule 4, Part 1, entry for Circumstances Code “C10742”

*omit entry for Circumstances Code “C10742” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C10742 | P10742 | CN10742 | Guselkumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 20 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration 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 within 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. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Circumstances Code “C11090”

*omit entry for Circumstances Code “C11090” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C11090 | P11090 | CN11090 | Tildrakizumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 28 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration 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 within 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.  At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Circumstances Code “C11096”

*omit entry for Circumstances Code “C11096” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C11096 | P11096 | CN11096 | Ixekizumab  Secukinumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration 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 within 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. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Circumstances Code “C11119”

*omit entry for Circumstances Code “C11119” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C11119 | P11119 | CN11119 | Ustekinumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 28 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  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.  At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration 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 within 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. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Circumstances Code “C11123”

*omit entry for Circumstances Code “C11123” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C11123 | P11123 | CN11123 | Tildrakizumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 28 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration 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 within 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.  At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Circumstances Code “C11130”

*omit entry for Circumstances Code “C11130” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C11130 | P11130 | CN11130 | Guselkumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 20 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration 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 within 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. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Circumstances Code “C11138”

*omit entry for Circumstances Code “C11138” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C11138 | P11138 | CN11138 | Ixekizumab  Secukinumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration 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 within 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. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Circumstances Code “C11153”

*omit entry for Circumstances Code “C11153” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C11153 | P11153 | CN11153 | Ustekinumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 28 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration 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 within 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. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, omit entry for Circumstances Code “C11178”
2. Schedule 4, Part 1, omit entry for Circumstances Code “C11181”
3. Schedule 4, Part 1, omit entry for Circumstances Code “C11183”
4. Schedule 4, Part 1, omit entry for Circumstances Code “C11185”
5. Schedule 4, Part 1, omit entry for Circumstances Code “C11229”
6. Schedule 4, Part 1, entry for Circumstances Code “C11704”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
7. Schedule 4, Part 1, entry for Circumstances Code “C11711”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
8. Schedule 4, Part 1, entry for Circumstances Code “C11715”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
9. Schedule 4, Part 1, entry for Circumstances Code “C11716”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
10. Schedule 4, Part 1, entry for Circumstances Code “C11717”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
11. Schedule 4, Part 1, entry for Circumstances Code “C11761”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
12. Schedule 4, Part 1, entry for Circumstances Code “C11762”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
13. Schedule 4, Part 1, entry for Circumstances Code “C11763”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
14. Schedule 4, Part 1, entry for Circumstances Code “C11767”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
15. Schedule 4, Part 1, omit entry for Circumstances Code “C11841”
16. Schedule 4, Part 1, omit entry for Circumstances Code “C11842”
17. Schedule 4, Part 1, entry for Circumstances Code “C11844”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
18. Schedule 4, Part 1, entry for Circumstances Code “C11846”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
19. Schedule 4, Part 1, omit entry for Circumstances Code “C11848”
20. Schedule 4, Part 1, entry for Circumstances Code “C11861”

*omit entry for Circumstances Code “C11861” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C11861 | P11861 | CN11861 | Adalimumab | Severe psoriatic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (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 major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The 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 a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  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. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Circumstances Code “C11892”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
2. Schedule 4, Part 1, entry for Circumstances Code “C11893”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
3. Schedule 4, Part 1, entry for Circumstances Code “C11897”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
4. Schedule 4, Part 1, entry for Circumstances Code “C11902”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
5. Schedule 4, Part 1, entry for Circumstances Code “C11924”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
6. Schedule 4, Part 1, entry for Circumstances Code “C11926”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
7. Schedule 4, Part 1, entry for Circumstances Code “C11945”

*omit entry for Circumstances Code “C11945” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C11945 | P11945 | CN11945 | Tofacitinib  Upadacitinib | Severe psoriatic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (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 major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  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. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, omit entry for Circumstances Code “C11950”
2. Schedule 4, Part 1, entry for Circumstances Code “C11958”

*omit entry for Circumstances Code “C11958” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C11958 | P11958 | CN11958 | Ixekizumab | Severe psoriatic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 20 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (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 major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  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. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Circumstances Code “C11964”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
2. Schedule 4, Part 1, entry for Circumstances Code “C12155”

*omit entry for Circumstances Code “C12155” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C12155 | P12155 | CN12155 | Adalimumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); 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) which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration 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 within 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. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Circumstances Code “C12212”

*omit entry for Circumstances Code “C12212” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C12212 | P12212 | CN12212 | Adalimumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); 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) which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration 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 within 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. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Circumstances Code “C12272”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
2. Schedule 4, Part 1, omit entry for Circumstances Code “C12275”
3. Schedule 4, Part 1, omit entry for Circumstances Code “C12278”
4. Schedule 4, Part 1, entry for Circumstances Code “C12306”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
5. Schedule 4, Part 1, entry for Circumstances Code “C12315”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
6. Schedule 4, Part 1, entry for Circumstances Code “C12399”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
7. Schedule 4, Part 1, entry for Circumstances Code “C12404”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
8. Schedule 4, Part 1, entry for Circumstances Code “C12405”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
9. Schedule 4, Part 1, entry for Circumstances Code “C12436”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
10. Schedule 4, Part 1, omit entry for Circumstances Code “C12439”
11. Schedule 4, Part 1, entry for Circumstances Code “C12450”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
12. Schedule 4, Part 1, entry for Circumstances Code “C12451”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
13. Schedule 4, Part 1, entry for Circumstances Code “C12609”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
14. Schedule 4, Part 1, entry for Circumstances Code “C12614”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
15. Schedule 4, Part 1, omit entry for Circumstances Code “C12624”
16. Schedule 4, Part 1, omit entry for Circumstances Code “C12625”
17. Schedule 4, Part 1, entry for Circumstances Code “C12630”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
18. Schedule 4, Part 1, entry for Circumstances Code “C12635”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
19. Schedule 4, Part 1, entry for Circumstances Code “C12639”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
20. Schedule 4, Part 1, entry for Circumstances Code “C12672”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
21. Schedule 4, Part 1, entry for Circumstances Code “C12676”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
22. Schedule 4, Part 1, entry for Circumstances Code “C12703”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
23. Schedule 4, Part 1, entry for Circumstances Code “C12704”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
24. Schedule 4, Part 1, entry for Circumstances Code “C12705”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
25. Schedule 4, Part 1, entry for Circumstances Code “C12711”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
26. Schedule 4, Part 1, entry for Circumstances Code “C12712”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
27. Schedule 4, Part 1, entry for Circumstances Code “C12713”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
28. Schedule 4, Part 1, entry for Circumstances Code “C12721”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
29. Schedule 4, Part 1, entry for Circumstances Code “C12722”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
30. Schedule 4, Part 1, entry for Circumstances Code “C12723”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
31. Schedule 4, Part 1, entry for Circumstances Code “C12725”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
32. Schedule 4, Part 1, entry for Circumstances Code “C12726”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
33. Schedule 4, Part 1, entry for Circumstances Code “C12731”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
34. Schedule 4, Part 1, entry for Circumstances Code “C12738”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
35. Schedule 4, Part 1, entry for Circumstances Code “C12749”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
36. Schedule 4, Part 1, entry for Circumstances Code “C12752”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
37. Schedule 4, Part 1, entry for Circumstances Code “C12755”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
38. Schedule 4, Part 1, entry for Circumstances Code “C12758”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
39. Schedule 4, Part 1, entry for Circumstances Code “C12760”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
40. Schedule 4, Part 1, entry for Circumstances Code “C12765”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
41. Schedule 4, Part 1, entry for Circumstances Code “C12768”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
42. Schedule 4, Part 1, entry for Circumstances Code “C12769”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
43. Schedule 4, Part 1, entry for Circumstances Code “C12770”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
44. Schedule 4, Part 1, entry for Circumstances Code “C12771”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
45. Schedule 4, Part 1, entry for Circumstances Code “C12774”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
46. Schedule 4, Part 1, entry for Circumstances Code “C12775”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
47. Schedule 4, Part 1, entry for Circumstances Code “C12779”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
48. Schedule 4, Part 1, entry for Circumstances Code “C12780”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
49. Schedule 4, Part 1, entry for Circumstances Code “C12784”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
50. Schedule 4, Part 1, entry for Circumstances Code “C12785”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
51. Schedule 4, Part 1, entry for Circumstances Code “C12789”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
52. Schedule 4, Part 1, entry for Circumstances Code “C12790”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
53. Schedule 4, Part 1, entry for Circumstances Code “C12791”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
54. Schedule 4, Part 1, entry for Circumstances Code “C12793”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
55. Schedule 4, Part 1, entry for Circumstances Code “C12798”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
56. Schedule 4, Part 1, entry for Circumstances Code “C12803”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
57. Schedule 4, Part 1, entry for Circumstances Code “C12805”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
58. Schedule 4, Part 1, entry for Circumstances Code “C12806”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
59. Schedule 4, Part 1, entry for Circumstances Code “C12809”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
60. Schedule 4, Part 1, entry for Circumstances Code “C12810”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
61. Schedule 4, Part 1, entry for Circumstances Code “C12812”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
62. Schedule 4, Part 1, entry for Circumstances Code “C12817”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
63. Schedule 4, Part 1, entry for Circumstances Code “C12820”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
64. Schedule 4, Part 1, entry for Circumstances Code “C12824”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
65. Schedule 4, Part 1, entry for Circumstances Code “C12826”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
66. Schedule 4, Part 1, entry for Circumstances Code “C12829”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
67. Schedule 4, Part 1, entry for Circumstances Code “C12831”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
68. Schedule 4, Part 1, entry for Circumstances Code “C12832”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
69. Schedule 4, Part 1, entry for Circumstances Code “C12834”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
70. Schedule 4, Part 1, entry for Circumstances Code “C12855”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
71. Schedule 4, Part 1, entry for Circumstances Code “C12857”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
72. Schedule 4, Part 1, entry for Circumstances Code “C12858”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
73. Schedule 4, Part 1, entry for Circumstances Code “C12860”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
74. Schedule 4, Part 1, entry for Circumstances Code “C12861”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
75. Schedule 4, Part 1, entry for Circumstances Code “C12866”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
76. Schedule 4, Part 1, entry for Circumstances Code “C12867”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
77. Schedule 4, Part 1, entry for Circumstances Code “C12869”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
78. Schedule 4, Part 1, entry for Circumstances Code “C12671”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
79. Schedule 4, Part 1, entry for Circumstances Code “C12772”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
80. Schedule 4, Part 1, entry for Circumstances Code “C12876”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
81. Schedule 4, Part 1, entry for Circumstances Code “C12877”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
82. Schedule 4, Part 1, entry for Circumstances Code “C12880”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
83. Schedule 4, Part 1, entry for Circumstances Code “C12882”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
84. Schedule 4, Part 1, entry for Circumstances Code “C12884”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
85. Schedule 4, Part 1, entry for Circumstances Code “C12886”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
86. Schedule 4, Part 1, entry for Circumstances Code “C12887”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
87. Schedule 4, Part 1, entry for Circumstances Code “C12899”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
88. Schedule 4, Part 1, omit entry for Circumstances Code “C12983”
89. Schedule 4, Part 1, omit entry for Circumstances Code “C12986”
90. Schedule 4, Part 1, omit entry for Circumstances Code “C13010”
91. Schedule 4, Part 1, omit entry for Circumstances Code “C13011”
92. Schedule 4, Part 1, omit entry for Circumstances Code “C13012”
93. Schedule 4, Part 1, omit entry for Circumstances Code “C13015”
94. Schedule 4, Part 1, omit entry for Circumstances Code “C13029”
95. Schedule 4, Part 1, entry for Circumstances Code “C13177”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
96. Schedule 4, Part 1, entry for Circumstances Code “C13184”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
97. Schedule 4, Part 1, entry for Circumstances Code “C13233”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
98. Schedule 4, Part 1, entry for Circumstances Code “C13250”
    1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
99. Schedule 4, Part 1, omit entry for Circumstances Code “C13327”
100. Schedule 4, Part 1, omit entry for Circumstances Code “C13377”
101. Schedule 4, Part 1, omit entry for Circumstances Code “C13491”
102. Schedule 4, Part 1, omit entry for Circumstances Code “C13496”
103. Schedule 4, Part 1, omit entry for Circumstances Code “C13497”
104. Schedule 4, Part 1, omit entry for Circumstances Code “C13499”
105. Schedule 4, Part 1, omit entry for Circumstances Code “C13500”
106. Schedule 4, Part 1, omit entry for Circumstances Code “C13502”
107. Schedule 4, Part 1, omit entry for Circumstances Code “C13505”
108. Schedule 4, Part 1, omit entry for Circumstances Code “C13506”
109. Schedule 4, Part 1, omit entry for Circumstances Code “C13510”
110. Schedule 4, Part 1, omit entry for Circumstances Code “C13512”
111. Schedule 4, Part 1, omit entry for Circumstances Code “C13514”
112. Schedule 4, Part 1, omit entry for Circumstances Code “C13515”
113. Schedule 4, Part 1, omit entry for Circumstances Code “C13575”
114. Schedule 4, Part 1, omit entry for Circumstances Code “C13576”
115. Schedule 4, Part 1, omit entry for Circumstances Code “C13577”
116. Schedule 4, Part 1, omit entry for Circumstances Code “C13582”
117. Schedule 4, Part 1, entry for Circumstances Code “C13598”

*omit entry for Circumstances Code “C13598” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C13598 | P13598 | CN13598 | Etanercept | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be at least 18 years of age;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.  To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.  The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration 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 within 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. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Circumstances Code “C13629”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
2. Schedule 4, Part 1, omit entry for Circumstances Code “C13631”
3. Schedule 4, Part 1, omit entry for Circumstances Code “C13634”
4. Schedule 4, Part 1, entry for Circumstances Code “C13646”

*omit entry for Circumstances Code “C13646” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C13646 | P13646 | CN13646 | Etanercept | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be at least 18 years of age;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.  To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration 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 within 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. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Circumstances Code “C13692”

*omit entry for Circumstances Code “C13692” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C13692 | P13692 | CN13692 | Infliximab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 22 weeks of treatment under this restriction;  Patient must be at least 18 years of age;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration 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 within 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. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Circumstances Code “C13719”

*omit entry for Circumstances Code “C13719” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C13719 | P13719 | CN13719 | Infliximab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 22 weeks of treatment under this restriction;  Patient must be at least 18 years of age;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.  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.  At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration 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 within 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. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, omit entry for Circumstances Code “C13852”
2. Schedule 4, Part 1, omit entry for Circumstances Code “C13863”
3. Schedule 4, Part 1, omit entry for Circumstances Code “C13864”
4. Schedule 4, Part 1, omit entry for Circumstances Code “C13865”
5. Schedule 4, Part 1, omit entry for Circumstances Code “C13866”
6. Schedule 4, Part 1, omit entry for Circumstances Code “C13877”
7. Schedule 4, Part 1, omit entry for Circumstances Code “C13890”
8. Schedule 4, Part 1, omit entry for Circumstances Code “C13891”
9. Schedule 4, Part 1, omit entry for Circumstances Code “C13929”
10. Schedule 4, Part 1, omit entry for Circumstances Code “C13930”
11. Schedule 4, Part 1, omit entry for Circumstances Code “C13986”
12. Schedule 4, Part 1, omit entry for Circumstances Code “C13993”
13. Schedule 4, Part 1, omit entry for Circumstances Code “C14007”
14. Schedule 4, Part 1, omit entry for Circumstances Code “C14009”
15. Schedule 4, Part 1, omit entry for Circumstances Code “C14054”
16. Schedule 4, Part 1, omit entry for Circumstances Code “C14101”
17. Schedule 4, Part 1, omit entry for Circumstances Code “C14126”
18. Schedule 4, Part 1, omit entry for Circumstances Code “C14127”
19. Schedule 4, Part 1, omit entry for Circumstances Code “C14129”
20. Schedule 4, Part 1, omit entry for Circumstances Code “C14130”
21. Schedule 4, Part 1, omit entry for Circumstances Code “C14131”
22. Schedule 4, Part 1, omit entry for Circumstances Code “C14132”
23. Schedule 4, Part 1, entry for Circumstances Code “C14370”

*omit entry for Circumstances Code “C14370” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C14370 | P14370 | CN14370 | Nusinersen | Spinal muscular atrophy (SMA)  Changing the prescribed therapy  Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated after the patient's 19th birthday; AND  Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; or  Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND  Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment; AND  Patient must be untreated with gene therapy; AND  Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.  Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.  The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, omit entry for Circumstances Code “C14384”
2. Schedule 4, Part 1, entry for Circumstances Code “C14396”

*omit entry for Circumstances Code “C14396” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C14396 | P14396 | CN14396 | Bimekizumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be at least 18 years of age;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); 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) which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration 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 within 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. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, omit entry for Circumstances Code “C14417”
2. Schedule 4, Part 1, entry for Circumstances Code “C14421”

*omit entry for Circumstances Code “C14421” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C14421 | P14421 | CN14421 | Nusinersen | Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)  Changing the prescribed therapy  Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated prior to the patient's 19th birthday for SMA type IIIB/IIIC; AND  Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; or  Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND  Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment; AND  Patient must be untreated with gene therapy; AND  Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.  Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.  The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Circumstances Code “C14437”

*omit entry for Circumstances Code “C14437” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C14437 | P14437 | CN14437 | Bimekizumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be at least 18 years of age;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); 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) which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration 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 within 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. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, omit entry for Circumstances Code “C14523”
2. Schedule 4, Part 1, omit entry for Circumstances Code “C14524”
3. Schedule 4, Part 1, omit entry for Circumstances Code “C14555”
4. Schedule 4, Part 1, omit entry for Circumstances Code “C14617”
5. Schedule 4, Part 1, omit entry for Circumstances Code “C14858”
6. Schedule 4, Part 1, omit entry for Circumstances Code “C14859”
7. Schedule 4, Part 1, omit entry for Circumstances Code “C14862”
8. Schedule 4, Part 1, omit entry for Circumstances Code “C14876”
9. Schedule 4, Part 1, omit entry for Circumstances Code “C14878”
10. Schedule 4, Part 1, omit entry for Circumstances Code “C14881”
11. Schedule 4, Part 1, omit entry for Circumstances Code “C14885”
12. Schedule 4, Part 1, omit entry for Circumstances Code “C14887”
13. Schedule 4, Part 1, omit entry for Circumstances Code “C14888”
14. Schedule 4, Part 1, omit entry for Circumstances Code “C14891”
15. Schedule 4, Part 1, omit entry for Circumstances Code “C14894”
16. Schedule 4, Part 1, omit entry for Circumstances Code “C14905”
17. Schedule 4, Part 1, omit entry for Circumstances Code “C14911”
18. Schedule 4, Part 1, omit entry for Circumstances Code “C14924”
19. Schedule 4, Part 1, omit entry for Circumstances Code “C14925”
20. Schedule 4, Part 1, omit entry for Circumstances Code “C14933”
21. Schedule 4, Part 1, omit entry for Circumstances Code “C14935”
22. Schedule 4, Part 1, omit entry for Circumstances Code “C14937”
23. Schedule 4, Part 1, omit entry for Circumstances Code “C14949”
24. Schedule 4, Part 1, omit entry for Circumstances Code “C14950”
25. Schedule 4, Part 1, omit entry for Circumstances Code “C14954”
26. Schedule 4, Part 1, omit entry for Circumstances Code “C14974”
27. Schedule 4, Part 1, omit entry for Circumstances Code “C14978”
28. Schedule 4, Part 1, omit entry for Circumstances Code “C14987”
29. Schedule 4, Part 1, omit entry for Circumstances Code “C14999”
30. Schedule 4, Part 1, omit entry for Circumstances Code “C15000”
31. Schedule 4, Part 1, omit entry for Circumstances Code “C15001”
32. Schedule 4, Part 1, omit entry for Circumstances Code “C15002”
33. Schedule 4, Part 1, omit entry for Circumstances Code “C15014”
34. Schedule 4, Part 1, entry for Circumstances Code “C15069”

*omit entry for Circumstances Code “C15069” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C15069 | P15069 | CN15069 | Nusinersen | Spinal muscular atrophy (SMA)  Continuing/maintenance treatment of either symptomatic Type I, II or IIIa SMA, or of a patient commenced on this drug under the pre-symptomatic SMA (1 or 2 copies of the SMN2 gene) listing  Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND  Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; or  Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition; AND  The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition; AND  The treatment must be given concomitantly with best supportive care for this condition; AND  The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug;  Patient must have been 18 years of age or younger at the time of initial treatment with this drug.  Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.  In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, omit entry for Circumstances Code “C15088”
2. Schedule 4, Part 1, entry for Circumstances Code “C15095”

*omit entry for Circumstances Code “C15095” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C15095 | P15095 | CN15095 | Risdiplam | Spinal muscular atrophy (SMA)  Continuing/maintenance treatment with this drug of either symptomatic Type I, II or IIIa SMA, or, pre-symptomatic SMA (1 or 2 copies of the SMN2 gene)  Patient must have previously received PBS-subsidised treatment with this drug for this condition; or  Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition; AND  The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition; AND  The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug; AND  The treatment must be given concomitantly with best supportive care for this condition; AND  Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic; AND  Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy;  Patient must have been 18 years of age or younger at the time of initial treatment with this drug.  Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.  In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required.  The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.  The approved Product Information recommended dosing is as follows  (i) 16 days to less than 2 months of age 0.15 mg/kg  (ii) 2 months to less than 2 years of age 0.20 mg/kg  (iii) 2 years of age and older weighing less than 20 kg 0.25 mg/kg  (iv) 2 years of age and older weighing 20 kg or more 5 mg  In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to  1 unit where (i) applies;  2 units where (ii) applies;  3 units where (iii) applies;  3 units where (iv) applies. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Circumstances Code “C15112”

*omit entry for Circumstances Code “C15112” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C15112 | P15112 | CN15112 | Nusinersen | Spinal muscular atrophy (SMA)  Continuing/maintenance treatment of a patient commenced on this drug under the pre-symptomatic SMA (3 copies of the SMN2 gene) listing  Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND  Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; or  Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition; AND  The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition; AND  The treatment must be given concomitantly with best supportive care for this condition; AND  The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug;  Patient must have been 18 years of age or younger at the time of initial treatment with this drug.  Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.  In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, omit entry for Circumstances Code “C15122”
2. Schedule 4, Part 1, omit entry for Circumstances Code “C15132”
3. Schedule 4, Part 1, omit entry for Circumstances Code “C15144”
4. Schedule 4, Part 1, omit entry for Circumstances Code “C15153”
5. Schedule 4, Part 1, entry for Circumstances Code “C15213”

*omit entry for Circumstances Code “C15213” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C15213 | P15213 | CN15213 | Risankizumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 28 weeks of treatment under this restriction.  Patient must be at least 18 years of age.  Must be treated by a dermatologist.  An adequate response to treatment is defined as:  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include:  (1) a completed authority prescription form(s); 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) which includes the following:  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration 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 within 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.  At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Circumstances Code “C15222”

*omit entry for Circumstances Code “C15222” and substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C15222 | P15222 | CN15222 | Risankizumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 28 weeks of treatment under this restriction.  Patient must be at least 18 years of age.  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include:  (1) a completed authority prescription form(s); 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) which includes the following:  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration 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 within 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.  At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, after entry for Circumstances Code “C15242”
   1. *insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C15249 | P15249 | CN15249 | Adalimumab | Moderate to severe hidradenitis suppurativa  Initial treatment - Initial 1 (new patient)  Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND  Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR  Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR  Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; AND  Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must not receive more than 16 weeks of treatment under this restriction.  Must be treated by a dermatologist.  Assessment of disease severity must be no more than 4 weeks old at the time of application.  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.  At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply  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) which includes:  (i) the Hurley stage grading; and  (ii) the AN count; and  (iii) the name of the antibiotic/s received for two separate courses each of three months; or  (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics. | Compliance with Written Authority Required procedures |
| C15257 | P15257 | CN15257 | Osimertinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Continuing treatment of second-line EGFR tyrosine kinase inhibitor therapy  The treatment must be as monotherapy; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while receiving treatment with this drug for this condition.  Patient must be undergoing continuing treatment with this drug as second-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed).  PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available). | Compliance with Authority Required procedures |
| C15261 | P15261 | CN15261 | Alogliptin  Linagliptin  Saxagliptin  Sitagliptin  Vildagliptin | Diabetes mellitus type 2  The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin; AND  The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.  Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor. | Compliance with Authority Required procedures - Streamlined Authority Code 15261 |
| C15263 | P15263 | CN15263 | Dulaglutide  Semaglutide | Diabetes mellitus type 2  Subsequent PBS-prescriptions for any GLP-1 receptor agonist  Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist. | Compliance with Authority Required procedures - Streamlined Authority Code 15263 |
| C15265 | P15265 | CN15265 | Dapagliflozin  Empagliflozin | Diabetes mellitus type 2  The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND  The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin; AND  The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.  Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor. | Compliance with Authority Required procedures - Streamlined Authority Code 15265 |
| C15267 | P15267 | CN15267 | Dapagliflozin with metformin  Empagliflozin with metformin | Diabetes mellitus type 2  The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND  The condition must be inadequately responsive to metformin.  Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor. | Compliance with Authority Required procedures - Streamlined Authority Code 15267 |
| C15269 | C15269 | CN15269 | Empagliflozin with linagliptin  Saxagliptin with dapagliflozin | Diabetes mellitus type 2  The treatment must be in combination with at least metformin; AND  The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DDP-4 inhibitor, an SGLT2 inhibitor.  Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor. | Compliance with Authority Required procedures - Streamlined Authority Code 15269 |
| C15270 | C15270 | CN15270 | Empagliflozin with linagliptin  Saxagliptin with dapagliflozin | Diabetes mellitus type 2  The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND  The treatment must be in combination with at least metformin; AND  The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DDP-4 inhibitor, an SGLT2 inhibitor.  Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor. | Compliance with Authority Required procedures - Streamlined Authority Code 15270 |
| C15276 | P15276 | CN15276 | Alogliptin with metformin  Linagliptin with metformin  Saxagliptin with metformin  Sitagliptin with metformin  Vildagliptin with metformin | Diabetes mellitus type 2  The condition must be inadequately responsive to metformin.  Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor. | Compliance with Authority Required procedures - Streamlined Authority Code 15276 |
| C15279 | P15279 | CN15279 | Secukinumab | Moderate to severe hidradenitis suppurativa  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)  Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  Patient must not receive more than 16 weeks of treatment under this restriction.  Must be treated by a dermatologist.  Assessment of disease severity must be no more than 4 weeks old at the time of application.  A response to treatment is defined as:  Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include:  (1) two completed authority prescription forms; 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) which includes:  (i) the Hurley stage grading; and  (ii) the AN count.  Two completed authority prescriptions should be submitted with every initial application for this drug.  One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
| C15280 | P15280 | CN1528 | Secukinumab | Moderate to severe hidradenitis suppurativa  Initial treatment - Initial 1 (new patient)  Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND  Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR  Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR  Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; AND  Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must not receive more than 16 weeks of treatment under this restriction.  Must be treated by a dermatologist.  Assessment of disease severity must be no more than 4 weeks old at the time of application.  An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 16 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.  The authority application must be made in writing and must include:  (1) two completed authority prescription forms; 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) which includes:  (i) the Hurley stage grading; and  (ii) the AN count; and  (iii) the name of the antibiotic/s received for two separate courses each of three months; or  (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics.  The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.  This restriction is intended for induction dosing only.  Two completed authority prescriptions should be submitted with every initial application for this drug.  One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.  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. | Compliance with Written Authority Required procedures |
| C15281 | P15281 | CN15281 | Osimertinib | Stage IB, II or IIIA non-small cell lung cancer  Adjuvant therapy  Patient must be both: (i) initiating treatment, (ii) untreated with EGFR-TKI for non small cell lung cancer; OR  Patient must be continuing existing PBS-subsidised treatment with this drug; OR  Patient must be both: (i) transitioning from existing non-PBS to PBS-subsidised supply of this drug, (ii) untreated with EGFR-TKI at the time this drug was initiated.  The treatment must be for the purpose of adjuvant therapy following surgical resection; AND  Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material; AND  Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug.  The treatment must be commenced within 26 weeks of surgery; AND  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.  Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 3 years in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the word 'cancelled'; where (i)/(ii) has occurred.  PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available). | Compliance with Authority Required procedures |
| C15283 | P15283 | CN15283 | Osimertinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Continuing treatment of first-line EGFR tyrosine kinase inhibitor therapy  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while receiving treatment with this drug for this condition.  Patient must be undergoing continuing treatment with this drug as first-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed).  PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available). | Compliance with Authority Required procedures |
| C15287 | P15287 | CN15287 | Alogliptin  Linagliptin  Saxagliptin  Sitagliptin  Vildagliptin | Diabetes mellitus type 2  The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND  The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin; AND  The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.  Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor. | Compliance with Authority Required procedures - Streamlined Authority Code 15287 |
| C15288 | P15288 | CN15288 | Alogliptin with metformin  Linagliptin with metformin  Saxagliptin with metformin  Sitagliptin with metformin  Vildagliptin with metformin | Diabetes mellitus type 2  The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND  The condition must be inadequately responsive to metformin.  Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor. | Compliance with Authority Required procedures - Streamlined Authority Code 15288 |
| C15289 | P15289 | CN15289 | Dapagliflozin with metformin  Empagliflozin with metformin | Diabetes mellitus type 2  The condition must be inadequately responsive to metformin.  Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor. | Compliance with Authority Required procedures - Streamlined Authority Code 15289 |
| C15290 | P15290 | CN15290 | Pioglitazone | Diabetes mellitus type 2  The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
| C15295 | P15295 | CN15295 | Secukinumab | Moderate to severe hidradenitis suppurativa  Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 2 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 16 weeks of treatment under this restriction.  Must be treated by a dermatologist.  Assessment of disease severity must be no more than 4 weeks old at the time of application.  A response to treatment is defined as:  Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include:  (1) two completed authority prescription forms; 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) which includes:  (i) the Hurley stage grading; and  (ii) the AN count.  Two completed authority prescriptions should be submitted with every initial application for this drug.  One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within 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. | Compliance with Written Authority Required procedures |
| C15296 | P15296 | CN15296 | Secukinumab | Moderate to severe hidradenitis suppurativa  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)  Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  Patient must not receive more than 16 weeks of treatment under this restriction.  Must be treated by a dermatologist.  Assessment of disease severity must be no more than 4 weeks old at the time of application.  A response to treatment is defined as:  Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include:  (1) two completed authority prescription forms; 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) which includes:  (i) the Hurley stage grading; and  (ii) the AN count.  Two completed authority prescriptions should be submitted with every initial application for this drug.  One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.  This restriction is intended for induction dosing only.  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 within this treatment cycle. | Compliance with Written Authority Required procedures |
| C15299 | P15299 | CN15299 | Osimertinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Initial treatment as first-line epidermal growth factor receptor tyrosine kinase inhibitor therapy  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have a WHO performance status of 2 or less; AND  Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR  Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal.  Patient must have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors.  PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available). | Compliance with Authority Required procedures |
| C15301 | P15301 | CN15301 | Dulaglutide  Semaglutide | Diabetes mellitus type 2  First PBS-prescription for this drug  The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin; AND  The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin; AND  Patient must not have achieved a clinically meaningful glycaemic response with an SGLT2 inhibitor; OR  Patient must have a contraindication/intolerance requiring treatment discontinuation of an SGLT2 inhibitor.  Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist. | Compliance with Authority Required procedures |
| C15303 | P15303 | CN15303 | Tafamidis | Transthyretin amyloid cardiomyopathy  Second and subsequent PBS-subsidised prescriptions for this drug  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have an estimated glomerular filtration rate (eGFR) greater than 25 mL/minute/1.73 m2; AND  The treatment must be ceased where the patient's heart failure has worsened to persistent New York Heart Association (NYHA) Class III/IV heart failure; AND  The treatment must be ceased where the patient has received any of: (i) a heart transplant, (ii) a liver transplant, (iii) an implanted ventricular assist device.  Must be treated by a medical practitioner who is any of the following: (i) a cardiologist, (ii) a consultant physician with experience in the management of amyloid disorders; this authority application must be sought by the same medical practitioner providing treatment.  Confirm whether heart failure has worsened to NYHA Class III/IV since the last authority application (yes/no).  If 'no', continued PBS subsidy is available.  If 'yes', continued PBS subsidy is available, but the prescriber must undertake a review of the patient within 3 months to determine whether the worsening heart failure was transient or persistent.  Where this subsequent clinical review finds that the heart failure persists as NYHA Class III/IV heart failure despite active treatment with this drug, then PBS subsidy is not available.  If heart failure has worsened to NYHA Class III/IV since the last authority application, no more than 2 repeat prescriptions must be prescribed. | Compliance with Authority Required procedures |
| C15307 | P15307 | CN15307 | Secukinumab | Moderate to severe hidradenitis suppurativa  Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 2 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 16 weeks of treatment under this restriction.  Must be treated by a dermatologist.  Assessment of disease severity must be no more than 4 weeks old at the time of application.  A response to treatment is defined as:  Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include:  (1) two completed authority prescription forms; 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) which includes:  (i) the Hurley stage grading; and  (ii) the AN count.  Two completed authority prescriptions should be submitted with every initial application for this drug.  One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.  This restriction is intended for induction dosing only.  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 within 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. | Compliance with Written Authority Required procedures |
| C15309 | P15309 | CN15309 | Adalimumab | Moderate to severe hidradenitis suppurativa  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)  Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  Patient must not receive more than 16 weeks of treatment under this restriction.  Must be treated by a dermatologist.  Assessment of disease severity must be no more than 4 weeks old at the time of application.  A response to treatment is defined as:  Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.  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) which includes:  (i) the Hurley stage grading; and  (ii) the AN count.  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 within this treatment cycle. | Compliance with Written Authority Required procedures |
| C15310 | P15310 | CN15310 | Osimertinib | Stage IB, II or IIIA non-small cell lung cancer  Adjuvant therapy  Patient must be continuing existing PBS-subsidised treatment with this drug; OR  Patient must be both: (i) transitioning from existing non-PBS to PBS-subsidised supply of this drug, (ii) untreated with EGFR-TKI at the time this drug was initiated.  The treatment must be for the purpose of adjuvant therapy following surgical resection; AND  Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material; AND  Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug.  The treatment must be commenced within 26 weeks of surgery; AND  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.  Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 3 years in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the word 'cancelled'; where (i)/(ii) has occurred.  PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available). | Compliance with Authority Required procedures |
| C15311 | P15311 | CN15311 | Dapagliflozin  Empagliflozin | Diabetes mellitus type 2  The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin; AND  The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.  Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor. | Compliance with Authority Required procedures - Streamlined Authority Code 15311 |
| C15313 | P15313 | CN15313 | Inclisiran | Familial heterozygous hypercholesterolaemia  Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements  Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2024; AND  The treatment must be in conjunction with dietary therapy and exercise; AND  The condition must have been confirmed by genetic testing prior to starting non-PBS-subsidised treatment with this drug for this condition; OR  The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6 prior to starting non-PBS-subsidised treatment with this drug for this condition; AND  Patient must have had an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease at the time non-PBS-subsidised treatment with this drug for this condition was initiated; OR  Patient must have had an LDL cholesterol level in excess of 5 millimoles per litre at the time non-PBS-subsidised treatment with this drug for this condition was initiated; AND  Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR  Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR  Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND  Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR  Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; AND  Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.  Must be treated by a specialist physician; OR  Must be treated by a physician who has consulted a specialist physician.  Symptomatic atherosclerotic cardiovascular disease is defined as:  (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or  (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or  (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).  The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated.  A clinically important product-related adverse event is defined as follows:  (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or  (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or  (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.  If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal.  In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.  The following must be stated at the time of application and documented in the patient's medical records:  (i) the qualifying Dutch Lipid Clinic Network Score; or  (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia  One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:  (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or  (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or  (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.  A patient may qualify for PBS-subsidised treatment under this restriction once only.  For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. | Compliance with Authority Required procedures |
| C15315 | P15315 | CN15315 | Inclisiran | Familial heterozygous hypercholesterolaemia  Initial treatment  The treatment must be in conjunction with dietary therapy and exercise; AND  The condition must have been confirmed by genetic testing; OR  The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6; AND  Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; OR  Patient must have an LDL cholesterol level in excess of 5 millimoles per litre; AND  Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR  Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR  Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND  Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR  Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; AND  Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.  Must be treated by a specialist physician; OR  Must be treated by a physician who has consulted a specialist physician.  Symptomatic atherosclerotic cardiovascular disease is defined as:  (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or  (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or  (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).  The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.  A clinically important product-related adverse event is defined as follows:  (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or  (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or  (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.  If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.  In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.  The following must be stated at the time of application and documented in the patient's medical records:  (i) the qualifying Dutch Lipid Clinic Network Score; or  (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia  One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:  (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or  (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or  (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. | Compliance with Authority Required procedures |
| C15316 | P15316 | CN15316 | Secukinumab | Moderate to severe hidradenitis suppurativa  Initial treatment - Initial 1 (new patient)  Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND  Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR  Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR  Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; AND  Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must not receive more than 16 weeks of treatment under this restriction.  Must be treated by a dermatologist.  Assessment of disease severity must be no more than 4 weeks old at the time of application.  An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 16 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.  The authority application must be made in writing and must include:  (1) two completed authority prescription forms; 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) which includes:  (i) the Hurley stage grading; and  (ii) the AN count; and  (iii) the name of the antibiotic/s received for two separate courses each of three months; or  (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics.  The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.  Two completed authority prescriptions should be submitted with every initial application for this drug.  One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.  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. | Compliance with Written Authority Required procedures |
| C15317 | P15317 | CN15317 | Secukinumab | Moderate to severe hidradenitis suppurativa  Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements  Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 June 2024; AND  Patient must have had a Hurley stage II or III with an abscess and inflammatory nodule (AN) count greater than or equal to 3 prior to starting treatment with this drug for this condition; AND  Patient must have demonstrated a response to treatment by achieving Hidradenitis Suppurativa Clinical Response (HiSCR) after 12 weeks of treatment if the patient has been treated with this drug for this condition for 12 weeks or longer; AND  Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; OR  Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; OR  Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; AND  Patient must not receive more than 24 weeks of treatment under this restriction.  Must be treated by a dermatologist.  A response to treatment is defined as:  Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.  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.  Assessment of disease severity must not have been more than 4 weeks old at the time treatment with this drug was initiated.  The authority application must be made in writing and must include:  (a) a completed authority prescription form; and  (b) completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:  (i) the Hurley stage grading; and  (ii) the AN count; and  (iii) the name of the antibiotic/s received for two separate courses each of three months; or  (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics  (v) the Hidradenitis Suppurativa Clinical Response (HiSCR) result if the patient has received 12 weeks or more of treatment.  A patient may qualify for PBS-subsidised treatment under this restriction once only.  For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. | Compliance with Written Authority Required procedures |
| C15319 | P15319 | CN15319 | Adalimumab | Moderate to severe hidradenitis suppurativa  Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 2 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 16 weeks of treatment under this restriction.  Must be treated by a dermatologist.  Assessment of disease severity must be no more than 4 weeks old at the time of application.  A response to treatment is defined as:  Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.  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) which includes:  (i) the Hurley stage grading; and  (ii) the AN count.  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 within 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. | Compliance with Written Authority Required procedures |
| C15321 | P15321 | CN15321 | Pioglitazone | Diabetes mellitus type 2 |  |
| C15323 | P15323 | CN15323 | Inclisiran | Non-familial hypercholesterolaemia  Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements  Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2024; AND  The treatment must be in conjunction with dietary therapy and exercise; AND  Patient must have had symptomatic atherosclerotic cardiovascular disease prior to starting non-PBS-subsidised treatment with this drug for this condition; AND  Patient must have had an LDL cholesterol level in excess of 1.8 millimoles per litre prior to starting non-PBS-subsidised treatment with this drug for this condition; AND  Patient must have had atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories) prior to starting non-PBS-subsidised treatment with this drug for this condition; OR  Patient must have had severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels prior to starting non-PBS-subsidised treatment with this drug for this condition; OR  Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years prior to starting non-PBS-subsidised treatment with this drug for this condition; OR  Patient must have had diabetes mellitus with microalbuminuria prior to starting non-PBS-subsidised treatment with this drug for this condition; OR  Patient must have had diabetes mellitus and be aged 60 years of more prior to starting non-PBS-subsidised treatment with this drug for this condition; OR  Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus that was present prior to starting non-PBS-subsidised treatment with this drug for this condition; OR  Patient must have had a Thrombolysis in Myocardial Infarction (TIMI) Risk Score for Secondary Prevention of 4 or higher prior to starting non-PBS-subsidised treatment with this drug for this condition; AND  Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR  Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR  Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND  Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR  Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; AND  Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.  Must be treated by a specialist physician; OR  Must be treated by a physician who has consulted a specialist physician.  Symptomatic atherosclerotic cardiovascular disease is defined as:  (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or  (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or  (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).  The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated.  A clinically important product-related adverse event is defined as follows:  (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or  (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or  (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.  If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal.  In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.  One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:  (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or  (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or  (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.  One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event:  (i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or  (ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or  (iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or  (iv) diabetes mellitus with microalbuminuria; or  (v) diabetes mellitus and age 60 years or more; or  (vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or  (vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher.  A patient may qualify for PBS-subsidised treatment under this restriction once only.  For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. | Compliance with Authority Required procedures |
| C15325 | P15325 | CN15325 | Secukinumab | Moderate to severe hidradenitis suppurativa  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have demonstrated a response to treatment with this drug for this condition.  Must be treated by a dermatologist.  A response to treatment is defined as:  Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.  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.  A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.  The authority application must be made in writing and must include:  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result. | Compliance with Written Authority Required procedures |
| C15326 | P15326 | CN15326 | Apremilast | Severe chronic plaque psoriasis  Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; OR  Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; OR  Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; AND  The condition must have caused significant interference with quality of life; AND  Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin, (iii) deucravacitinib.  Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; OR  Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar; OR  Must be treated by a general practitioner where there is agreement to continue treatment (not initiate treatment) with one of the above practitioner types.  Patient must be at least 18 years of age.  For patients who do not demonstrate an adequate response to apremilast, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.  This assessment must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 15326 |
| C15328 | P15328 | CN15328 | Secukinumab | Moderate to severe hidradenitis suppurativa  Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR  Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND  The treatment must provide no more than the balance of up to 16 weeks treatment.  Must be treated by a dermatologist. | Compliance with Authority Required procedures |
| C15329 | P15329 | CN15329 | Osimertinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Initial treatment as second-line EGFR tyrosine kinase inhibitor therapy  Patient must not have previously received this drug for this condition; AND  The treatment must be as monotherapy; AND  Patient must have a WHO performance status of 2 or less; AND  The condition must have progressed on or after prior epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) therapy as first line treatment for this condition; AND  Patient must have evidence of EGFR T790M mutation in tumour material at the point of progression on or after first line EGFR TKI treatment.  PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available). | Compliance with Authority Required procedures |
| C15330 | P15330 | CN15330 | Deucravacitinib | Severe chronic plaque psoriasis  Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; OR  Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; OR  Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; AND  The condition must have caused significant interference with quality of life; AND  Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin, (iii) apremilast.  Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; OR  Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar; OR  Must be treated by a general practitioner where there is agreement to continue treatment (not initiate treatment) with one of the above practitioner types.  Patient must be at least 18 years of age.  For patients who do not demonstrate an adequate response to apremilast, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.  This assessment must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 15330 |
| C15331 | P15331 | CN15331 | Inclisiran | Non-familial hypercholesterolaemia  Initial treatment  The treatment must be in conjunction with dietary therapy and exercise; AND  Patient must have symptomatic atherosclerotic cardiovascular disease; AND  Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre; AND  Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); OR  Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; OR  Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; OR  Patient must have diabetes mellitus with microalbuminuria; OR  Patient must have diabetes mellitus and be aged 60 years or more; OR  Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR  Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher; AND  Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR  Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR  Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND  Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR  Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; AND  Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.  Must be treated by a specialist physician; OR  Must be treated by a physician who has consulted a specialist physician.  Symptomatic atherosclerotic cardiovascular disease is defined as:  (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or  (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or  (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).  The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.  A clinically important product-related adverse event is defined as follows:  (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or  (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or  (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.  If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.  In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.  One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:  (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or  (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or  (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.  One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event:  (i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or  (ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or  (iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or  (iv) diabetes mellitus with microalbuminuria; or  (v) diabetes mellitus and age 60 years or more; or  (vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or  (vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher. | Compliance with Authority Required procedures |

1. Schedule 4, Part 2, after entry for Variation Code V15025

*insert:*

|  |  |  |
| --- | --- | --- |
| V15303 | Tafamidis | If heart failure has worsened to NYHA Class III/IV since the last authority application, no more than 2 repeat prescriptions must be prescribed. |

1. Schedule 5, entry for Abacavir with lamivudine

*substitute:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Abacavir with lamivudine | GRP-21981 | Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg | Oral | ABACAVIR/LAMIVUDINE 600/300 SUN Abacavir/Lamivudine Mylan Abacavir/Lamivudine Viatris  Kivexa |

1. Schedule 5, entry for Ambrisentan in the form Tablet 5 mg
   1. *omit from the column headed “Brand”:* **Ambrisentan Mylan**
2. Schedule 5, entry for Amoxicillin in the form Capsule 500 mg (as trihydrate)

*omit from the column headed* *“Schedule Equivalent Group”:* GRP- 20241 *substitute:* GRP-20241

1. Schedule 5, entry for Anastrozole

*omit from the column headed “Brand”:* **Arimidex**

1. Schedule 5, entry for Azacitidine
   1. *insert in alphabetical order in the column headed “Brand”:* **AZACITIDINE EUGIA**
2. Schedule 5, entry for Benzathine benzylpenicillin in the form Powder for injection 1,200,000 units with diluent 5 mL (S19A)

*insert in alphabetical order in the column headed “Brand”:* Extencilline Benzathine Benzylpenicillin (France)

1. Schedule 5, entry for Bosentan in each of the forms: Tablet 125 mg (as monohydrate); and Tablet 62.5 mg (as monohydrate)
   1. *omit from the column headed “Brand”:* Tracleer
2. Schedule 5, omit entry for Cefepime
3. Schedule 5, entry for Ceftriaxone
   1. *substitute:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Ceftriaxone | GRP-21683 | Powder for injection 2 g (as sodium) | Injection | Ceftriaxone Alphapharm Ceftriaxone Viatris |

1. Schedule 5, entry for Dicloxacillin in the form Capsule 250 mg (as sodium)
   1. *insert in alphabetical order in the column headed “Brand”:* **DICLOXACILLIN VIATRIS 250**
2. Schedule 5, entry for Dosulepin in the form Capsule containing dosulepin hydrochloride 25 mg
   1. *omit from the column headed “Brand”:* **Dosulepin Mylan**
3. Schedule 5, entry for Enalapril in the form Tablet containing enalapril maleate 10 mg

*omit from the column headed “Brand”:* Enalapril generichealth

1. Schedule 5, entry for Enalapril in the form Tablet containing enalapril maleate 5 mg

*omit from the column headed “Brand”:* Enalapril generichealth

1. Schedule 5, after entry for Estradiol
   1. *insert:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Estradiol | GRP-28649 | Transdermal patches 585 micrograms, 8 | Transdermal | Estradiol Transdermal System (Sandoz, USA) Estradot 37.5 |
| Estradiol | GRP-28651 | Transdermal patches 1.17 mg, 8 | Transdermal | Estradiol Transdermal System (Sandoz, USA) Estradot 75 |
| Estradiol | GRP-28652 | Transdermal patches 1.56 mg, 8 | Transdermal | Estradiol Transdermal System (Sandoz, USA) Estradot 100 |

1. Schedule 5, entry for Fluvoxamine
   1. *substitute:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Fluvoxamine | GRP-19862 | Tablet containing fluvoxamine maleate 100 mg | Oral | APO-Fluvoxamine Faverin 100 Luvox Movox 100 |
| Fluvoxamine | GRP-19729 | Tablet containing fluvoxamine maleate 50 mg | Oral | APO-Fluvoxamine Faverin 50 Luvox Movox 50 |

1. Schedule 5, entry for Fosinopril
   1. *substitute:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Fosinopril | GRP-19785 | Tablet containing fosinopril sodium 10 mg | Oral | APO-Fosinopril Monace 10 |
| Fosinopril | GRP-19769 | Tablet containing fosinopril sodium 20 mg | Oral | APO-Fosinopril Monace 20 |

1. Schedule 5, entry for Furosemide in the form Tablet 20 mg
   1. *insert in alphabetical order in the column headed “Brand”:* **UREMIDE 20**
2. Schedule 5, entry for Lamivudine with zidovudine
   1. *omit from the column headed “Brand”:* **Lamivudine 150 mg + Zidovudine 300 mg Alphapharm**
3. Schedule 5, entry for Lercanidipine
   1. *substitute:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Lercanidipine | GRP-19911 | Tablet containing lercanidipine hydrochloride 10 mg | Oral | BTC Lercanidipine Lercan Lercanidipine APOTEX Zanidip Zircol 10 |
| Lercanidipine | GRP-19829 | Tablet containing lercanidipine hydrochloride 20 mg | Oral | ARX-LERCANIDIPINE  BTC Lercanidipine Lercan Lercanidipine APOTEX Zanidip Zircol 20 |

1. Schedule 5, entry for Medroxyprogesterone
   1. *substitute:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Medroxyprogesterone | GRP-19676 | Tablet containing medroxyprogesterone acetate 10 mg | Oral | Provera Ralovera |
| Medroxyprogesterone | GRP-19872 | Tablet containing medroxyprogesterone acetate 5 mg | Oral | Provera Ralovera |
| Medroxyprogesterone | GRP-28650 | Injection containing medroxyprogesterone acetate 150 mg in 1 mL | Injection | Depo-Provera Depo-Ralovera |
| Medroxyprogesterone | GRP-28650 | Injection containing medroxyprogesterone acetate 150 mg in 1 mL pre-filled syringe | Injection | Depo-Provera |

1. Schedule 5, entry for Methotrexate in each of the forms: Tablet 10 mg; and Tablet 2.5 mg
   1. *insert in alphabetical order in the column headed “Brand”:* **ARX-Methotrexate**
2. Schedule 5, entry for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg

*omit from the column headed “Brand”:* Noumed Mycophenolate

1. Schedule 5, omit entry for Naltrexone
2. Schedule 5, entry for Nebivolol in each of the forms: Tablet 1.25 mg (as hydrochloride); and Tablet 10 mg (as hydrochloride)
   1. *omit from the column headed “Brand”:* **Nebivolol Viatris**
3. Schedule 5, entry for Olanzapine
   1. *substitute:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Olanzapine | GRP-15921 | Tablet 5 mg | Oral | NOUMED OLANZAPINE Olanzapine APOTEX Olanzapine RBX Olanzapine Sandoz Ozin 5 PRYZEX Zypine Zyprexa |
| Olanzapine | GRP-15513 | Tablet 10 mg | Oral | APO-OLANZAPINE NOUMED OLANZAPINE Olanzapine APOTEX Olanzapine RBX Olanzapine Sandoz Ozin 10 PRYZEX Zypine Zyprexa |
| Olanzapine | GRP-15723 | Tablet 10 mg (orally disintegrating) | Oral | APO-Olanzapine ODT Olanzapine ODT generichealth 10 Olanzapine Sandoz ODT 10 PRYZEX ODT Zypine ODT |
| Olanzapine | GRP-15723 | Wafer 10 mg | Oral | Zyprexa Zydis |
| Olanzapine | GRP-15953 | Tablet 15 mg (orally disintegrating) | Oral | APO-Olanzapine ODT Olanzapine Sandoz ODT 15 PRYZEX ODT Zypine ODT |
| Olanzapine | GRP-15953 | Wafer 15 mg | Oral | Zyprexa Zydis |
| Olanzapine | GRP-15492 | Tablet 2.5 mg | Oral | NOUMED OLANZAPINE Olanzapine APOTEX Olanzapine RBX Olanzapine Sandoz Ozin 2.5 PRYZEX Zypine Zyprexa |
| Olanzapine | GRP-15643 | Tablet 20 mg (orally disintegrating) | Oral | APO-Olanzapine ODT Olanzapine Sandoz ODT 20 PRYZEX ODT Zypine ODT |
| Olanzapine | GRP-15643 | Wafer 20 mg | Oral | Zyprexa Zydis |
| Olanzapine | GRP-15797 | Tablet 5 mg (orally disintegrating) | Oral | APO-Olanzapine ODT Olanzapine Sandoz ODT 5 PRYZEX ODT Zypine ODT |
| Olanzapine | GRP-15797 | Wafer 5 mg | Oral | Zyprexa Zydis |
| Olanzapine | GRP-15884 | Tablet 7.5 mg | Oral | APO-OLANZAPINE NOUMED OLANZAPINE Olanzapine APOTEX Olanzapine RBX Olanzapine Sandoz Ozin 7.5 PRYZEX Zypine Zyprexa |

1. Schedule 5, entry for Olmesartan with amlodipine and hydrochlorothiazide in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 12.5 mg
   1. *omit from the column headed “Schedule Equivalent Group”:* GRP- 23700 *substitute:* GRP-23700
2. Schedule 5, entry for Olmesartan with amlodipine and hydrochlorothiazide in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg
   1. *omit from the column headed “Schedule Equivalent Group”:* GRP- 23703 *substitute:* GRP-23703
3. Schedule 5, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg
   1. *insert in alphabetical order in the column headed “Brand”:* **Ondansetron ODT Viatris**
4. Schedule 5, entry for Ondansetron in each of the forms: Tablet 4 mg (as hydrochloride dihydrate); and Tablet 8 mg (as hydrochloride dihydrate)
   1. *insert in alphabetical order in the column headed “Brand”:* **Ondansetron Tablets Viatris**
5. Schedule 5, entry for Perindopril in each of the forms: Tablet containing perindopril arginine 10 mg; Tablet containing perindopril arginine 2.5 mg; and Tablet containing perindopril arginine 5 mg
   1. *insert in alphabetical order in the column headed “Brand”:* **Perindopril Arginine Sandoz**
6. Schedule 5, entry for Pioglitazone in each of the forms: Tablet 30 mg (as hydrochloride); and Tablet 45 mg (as hydrochloride)
7. *omit from the column headed “Brand”:* NOUMED PIOGLITAZONE
8. *omit from the column headed “Brand”:* Pioglitazone Sandoz
9. Schedule 5, entry for Plerixafor

*insert in alphabetical order in the column headed “Brand”:* PLERIXAFOR EUGIA

1. Schedule 5, entry for Quetiapine in each of the forms: Tablet (modified release) 150 mg (as fumarate); Tablet (modified release) 200 mg (as fumarate); Tablet (modified release) 300 mg (as fumarate); Tablet (modified release) 400 mg (as fumarate); and Tablet (modified release) 50 mg (as fumarate)
   1. *insert in alphabetical order in the column headed “Brand”:* **Quetiapine Sandoz XR**
2. Schedule 5, entry for Ramipril in the form Tablet 2.5 mg
   1. *insert in alphabetical order in the column headed “Brand”:* **Ramipril Viatris**
3. Schedule 5, entry for Rosuvastatin in the form Tablet 10 mg (as calcium)
4. *omit from the column headed “Schedule Equivalent Group”:* **GRP-19551** *substitute:* **GRP-19558**
5. *insert in alphabetical order in the column headed “Brand”:* **APO-Rosuvastatin**
6. *omit from the column headed “Brand”:* **Noumed Rosuvastatin**
7. Schedule 5, entry for Rosuvastatin in the form Tablet 20 mg (as calcium)
8. *omit from the column headed “Schedule Equivalent Group”:* **GRP-19553** *substitute:* **GRP-19557**
9. *omit from the column headed “Brand”:* **Noumed Rosuvastatin**
10. Schedule 5, entry for Rosuvastatin in the form Tablet 40 mg (as calcium)
11. *omit from the column headed “Schedule Equivalent Group”:* **GRP-19550** *substitute:* **GRP-19562**
12. *omit from the column headed “Brand”:* **Noumed Rosuvastatin**
13. Schedule 5, entry for Rosuvastatin in the form Tablet 5 mg (as calcium)
14. *omit from the column headed “Schedule Equivalent Group”:* **GRP-19552** *substitute:* **GRP-19569**
15. *omit from the column headed “Brand”:* **Noumed Rosuvastatin**
16. Schedule 5, entry for Sitagliptin in the form Tablet 100 mg

*omit from the column headed “Schedule Equivalent Group”:* GRP-26496 *substitute:* GRP-26498

1. Schedule 5, entry for Sitagliptin in the form Tablet 25 mg

*omit from the column headed “Schedule Equivalent Group”:* GRP-26495 *substitute:* GRP-26497

1. Schedule 5, entry for Sitagliptin with metformin in the form Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride

*omit from the column headed “Schedule Equivalent Group”:* GRP-26455 *substitute:* GRP-26459

1. Schedule 5, entry for Sitagliptin with metformin in the form Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride

*omit from the column headed “Schedule Equivalent Group”:* GRP-26448 *substitute:* GRP-26454

1. Schedule 5, entry for Sumatriptan in the form Tablet 50 mg (as succinate)

*insert in alphabetical order in the column headed “Brand”:* IMIGRAN MIGRAINE

1. Schedule 5, after entry for Teriparatide in the form Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen

*insert:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Testosterone | GRP-28648 | I.M. injection containing testosterone undecanoate 1,000 mg in 4 mL | Injection | Reandron 1000 Testosterone ADVZ 1000 |

1. Schedule 5, entry for Valaciclovir in the form Tablet 500 mg (as hydrochloride)
2. *omit from the column headed “Schedule Equivalent Group”:* GRP-19634 *substitute:* GRP-19726
3. *omit from the column headed “Brand”:* NOUMED VALACICLOVIR