

PB 24 of 2025

National Health (Listing of Pharmaceutical Benefits) Amendment (April Update) Instrument 2025

National Health Act 1953

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

Dated 27 March 2025

**REBECCA RICHARDSON**  
Assistant Secretary  
Pricing and PBS Policy Branch  
Technology Assessment and Access Division

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*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 (April Update) Instrument 2025*.

(2) This Instrument may also be cited as PB 24 of 2025.

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 April 2025* | *1 April 2025* |

Note: This table relates only to the provisions of this instrument as originally made.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

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

3. Authority

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

4. Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

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

[1] Schedule 1, Part 1, entry for Adalimumab in the form Injection 20 mg in 0.4 mL pre-filled syringe [Brand: Abrilada; Maximum Quantity: 2; Number of Repeats: 0]

(a) insert in numerical order in the column headed “Circumstances”: C15473

(b) insert in numerical order in the column headed “Purposes”: P15473

[2] Schedule 1, Part 1, entry for Adalimumab in the form Injection 20 mg in 0.4 mL pre-filled syringe [Brand: Abrilada; Maximum Quantity: 2; Number of Repeats: 5]

(a) insert in numerical order in the column headed “Circumstances”: C15445 C15446 C15450

(b) insert in numerical order in the column headed “Purposes”: P15445 P15446 P15450

[3] Schedule 1, Part 1, after entry for Adalimumab in the form Injection 20 mg in 0.4 mL pre-filled syringe [Brand: Abrilada; Maximum Quantity: 2; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adalimumab | Injection 20 mg in 0.4 mL pre-filled syringe | Injection | Abrilada | PF | MP | C15474 C15489 | P15474 P15489 | 2 | 6 |  | 2 |  |  |

[4] Schedule 1, Part 1, entry for Adalimumab in the form Injection 20 mg in 0.4 mL pre-filled syringe [Brand: Amgevita; Maximum Quantity: 2; Number of Repeats: 0]

(a) insert in numerical order in the column headed “Circumstances”: C15473

(b) insert in numerical order in the column headed “Purposes”: P15473

[5] Schedule 1, Part 1, entry for Adalimumab in the form Injection 20 mg in 0.4 mL pre-filled syringe [Brand: Amgevita; Maximum Quantity: 2; Number of Repeats: 5]

(a) insert in numerical order in the column headed “Circumstances”: C15445 C15446 C15450

(b) insert in numerical order in the column headed “Purposes”: P15445 P15446 P15450

[6] Schedule 1, Part 1, after entry for Adalimumab in the form Injection 20 mg in 0.4 mL pre-filled syringe [Brand: Amgevita; Maximum Quantity: 2; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adalimumab | Injection 20 mg in 0.4 mL pre-filled syringe | Injection | Amgevita | XT | MP | C15474 C15489 | P15474 P15489 | 2 | 6 |  | 1 |  |  |

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

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled syringe | Injection | Hyrimoz | SZ | MP | C11713 C15473 | P11713 P15473 | 2 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled syringe | Injection | Hyrimoz | SZ | MP | C12120 C14061 C14063 C14064 C14107 C14136 | See Note 3 | See Note 3 | See Note 3 |  | 2 |  | C(100) |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled syringe | Injection | Hyrimoz | SZ | MP | C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 2 | 2 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled syringe | Injection | Hyrimoz | SZ | MP | C9064 C9386 C11861 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673 | P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 | 2 | 3 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled syringe | Injection | Hyrimoz | SZ | MP | C11107 C12155 C12212 C13556 C13612 C14377 C14378 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled syringe | Injection | Hyrimoz | SZ | MP | C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11711 C11717 C11718 C11767 C11853 C11865 C11867 C11903 C11906 C11966 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C15450 | P11523 P11524 P11579 P11604 P11606 P11631 P11635 P11704 P11711 P11717 P11718 P11767 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P15450 | 2 | 5 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled syringe | Injection | Hyrimoz | SZ | MP | C15474 C15489 | P15474 P15489 | 2 | 6 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled syringe | Injection | Hyrimoz | SZ | MP | C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 6 | 0 |  | 2 |  |  |

[8] Schedule 1, Part 1, entries for Adefovir

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adefovir | Tablet containing adefovir dipivoxil 10 mg | Oral | APO-Adefovir | TX | MP NP | C4490 C4510 |  | 60 | 5 |  | 30 |  | D(100) |

[9] Schedule 1, Part 1, after entry for Amino acid formula with fat, carbohydrate without valine, leucine and isoleucine

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Amino acid formula with fat, carbohydrate, vitamins and minerals without phenylalanine | Tablets (modified release), 54 g protein per 100 g, 100 g, pack of 6 (PKU Easy Microtabs Plus) | Oral | PKU Easy Microtabs Plus | OH | MP NP | C5970 |  | 7 | 5 |  | 1 |  |  |

[10] Schedule 1, Part 1, after entry for Amino acid formula with vitamins and minerals without lysine and low in tryptophan in the form Oral powder 500 g (XLYS, LOW TRY Maxamum)

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Amino acid formula with vitamins and minerals without lysine and low in tryptophan | Sachets containing oral powder 12.5 g, pack of 30 (GA explore5) | Oral | GA explore5 | VF | MP NP | C5323 C11482 |  | 8 | 5 |  | 1 |  |  |

[11] Schedule 1, Part 1, after entry for Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine in the form Oral powder 400 g (MMA/PA Anamix infant)

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine | Sachets containing oral powder 12.5 g, pack of 30 (MMA/PA explore5) | Oral | MMA/PA explore5 | VF | MP NP | C5986 C6055 |  | 8 | 5 |  | 1 |  |  |

[12] Schedule 1, Part 1, omit entry for Amino acid formula with vitamins and minerals, without phenylalanine, tyrosine and supplemented with arachidonic acid and docosahexaenoic acid

[13] Schedule 1, Part 1, after entry for Amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid in the form Sachets containing oral powder 25 g, 30 (PKU Explore 10)

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Amino acid formula with vitamins and minerals, without phenylalanine, tyrosine and supplemented with arachidonic acid and docosahexaenoic acid | Sachets containing oral powder 12.5 g, 30 (TYR explore5) | Oral | TYR explore5 | VF | MP NP | C5533 |  | 8 | 5 |  | 1 |  |  |

[14] Schedule 1, Part 1, entries for Aripiprazole in the form Tablet 15 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Aripiprazole | Tablet 15 mg | Oral | Aripic Aripiprazole | LR | MP NP | C4246 |  | 30 | 5 |  | 30 |  |  |

[15] Schedule 1, Part 1, entries for Aripiprazole in the form Tablet 20 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Aripiprazole | Tablet 20 mg | Oral | Aripic Aripiprazole | LR | MP NP | C4246 |  | 30 | 5 |  | 30 |  |  |

[16] Schedule 1, Part 1, entries for Aripiprazole in the form Tablet 30 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Aripiprazole | Tablet 30 mg | Oral | Aripic Aripiprazole | LR | MP NP | C4246 |  | 30 | 5 |  | 30 |  |  |

[17] Schedule 1, Part 1, entries for Bevacizumab in the form Solution for I.V. infusion 100 mg in 4 mL

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bevacizumab | Solution for I.V. infusion 100 mg in 4 mL | Injection | Bevaciptin | LR | MP |  |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

[18] Schedule 1, Part 1, entries for Bevacizumab in the form Solution for I.V. infusion 400 mg in 16 mL

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bevacizumab | Solution for I.V. infusion 400 mg in 16 mL | Injection | Bevaciptin | LR | MP |  |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

[19] Schedule 1, Part 1, entry for Bimekizumab in the form Injection 160 mg in 1 mL single use pre-filled pen [Maximum Quantity: 2; Number of Repeats: 1]

(a) omit from the column headed “Circumstances”: C15950

(b) insert in numerical order in the column headed “Circumstances”: C16396

(c) omit from the column headed “Purposes”: P15950

(d) insert in numerical order in the column headed “Purposes”: P16396

[20] Schedule 1, Part 1, entries for Carmellose

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Carmellose | Eye drops containing carmellose sodium 5 mg per mL, single dose units 0.4 mL, 30 | Application to the eye | Cellufresh | VE | MP NP AO | C6172 | P6172 | 3 | 5 |  | 1 |  |  |
| Carmellose | Eye drops containing carmellose sodium 5 mg per mL, single dose units 0.4 mL, 31 | Application to the eye | Cellufresh | VE | MP NP AO | C15559 | P15559 | 6 | 5 |  | 1 |  |  |
| Carmellose | Eye drops containing carmellose sodium 10 mg per mL, single dose units 0.4 mL, 30 | Application to the eye | Celluvisc | VE | MP NP AO | C6172 | P6172 | 3 | 5 |  | 1 |  |  |
| Carmellose | Eye drops containing carmellose sodium 10 mg per mL, single dose units 0.4 mL, 31 | Application to the eye | Celluvisc | VE | MP NP AO | C15559 | P15559 | 6 | 5 |  | 1 |  |  |

[21] Schedule 1, Part 1, entries for Clonazepam

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Clonazepam | Tablet 2 mg (S19A) | Oral | Clonazepam USP (Advagen Pharma, USA) | LM | MP NP | C11746 | P11746 | 100 | 3 |  | 100 |  |  |
| Clonazepam | Tablet 2 mg (S19A) | Oral | Clonazepam USP (Advagen Pharma, USA) | LM | MP NP | C6296 | P6296 | 200 | 2 |  | 100 |  |  |

[22] Schedule 1, Part 1, entries for Clopidogrel with aspirin

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Clopidogrel with aspirin | Tablet 75 mg (as hydrogen sulfate)-100 mg | Oral | Clopidogrel Winthrop plus aspirin | WA | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Clopidogrel with aspirin | Tablet 75 mg (as hydrogen sulfate)-100 mg | Oral | Clopidogrel Winthrop plus aspirin | WA | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[23] Schedule 1, Part 1, entries for Dabrafenib

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dabrafenib | Capsule 50 mg (as mesilate) | Oral | Tafinlar | NV | MP | C10130 C10148 C10157 | P10130 P10148 P10157 | 120 | 3 |  | 120 |  |  |
| Dabrafenib | Capsule 50 mg (as mesilate) | Oral | Tafinlar | NV | MP | C6013 | P6013 | 120 | 5 |  | 120 |  |  |
| Dabrafenib | Capsule 50 mg (as mesilate) | Oral | Tafinlar | NV | MP | C16385 | P16385 | 240 | 1 |  | 120 |  |  |
| Dabrafenib | Capsule 50 mg (as mesilate) | Oral | Tafinlar | NV | MP | C16358 C16360 C16377 C16378 C16389 | P16358 P16360 P16377 P16378 P16389 | 240 | 3 |  | 120 |  |  |
| Dabrafenib | Capsule 75 mg (as mesilate) | Oral | Tafinlar | NV | MP | C16385 | P16385 | 120 | 1 |  | 120 |  |  |
| Dabrafenib | Capsule 75 mg (as mesilate) | Oral | Tafinlar | NV | MP | C10130 C10148 C10157 C16358 C16360 C16377 C16378 C16389 | P10130 P10148 P10157 P16358 P16360 P16377 P16378 P16389 | 120 | 3 |  | 120 |  |  |
| Dabrafenib | Capsule 75 mg (as mesilate) | Oral | Tafinlar | NV | MP | C6013 | P6013 | 120 | 5 |  | 120 |  |  |
| Dabrafenib | Tablet (dispersible) 10 mg (as mesilate) | Oral | Tafinlar | NV | MP | C16385 | P16385 | 840 | 1 |  | 420 |  |  |
| Dabrafenib | Tablet (dispersible) 10 mg (as mesilate) | Oral | Tafinlar | NV | MP | C16358 C16360 C16377 C16378 C16389 | P16358 P16360 P16377 P16378 P16389 | 840 | 3 |  | 420 |  |  |

[24] Schedule 1, Part 1, entries for Doxorubicin

omit from the column headed “Manner of Administration” (all instances): Injection intravesical  substitute (all instances): Injection/intravesical

[25] Schedule 1, Part 1, entry for Empagliflozin in the form Tablet 10 mg [Maximum Quantity: 30; Number of Repeats: 5]

(a) insert in numerical order in the column headed “Circumstances”: C16220

(b) insert in numerical order in the column headed “Purposes”: P16220

[26] Schedule 1, Part 1, entry for Empagliflozin in the form Tablet 10 mg [Maximum Quantity: 60; Number of Repeats: 5]

(a) insert in numerical order in the column headed “Circumstances”: C16164

(b) insert in numerical order in the column headed “Purposes”: P16164

[27] Schedule 1, Part 1, entry for Empagliflozin in the form Tablet 25 mg [Maximum Quantity: 30; Number of Repeats: 5]

(a) insert in numerical order in the column headed “Circumstances”: C16220

(b) insert in numerical order in the column headed “Purposes”: P16220

[28] Schedule 1, Part 1, entry for Empagliflozin in the form Tablet 25 mg [Maximum Quantity: 60; Number of Repeats: 5]

(a) insert in numerical order in the column headed “Circumstances”: C16164

(b) insert in numerical order in the column headed “Purposes”: P16164

[29] Schedule 1, Part 1, entry for Empagliflozin with metformin in the form Tablet containing 5 mg empagliflozin with 1 g metformin hydrochloride [Maximum Quantity: 60; Number of Repeats: 5]

(a) insert in numerical order in the column headed “Circumstances”: C16158

(b) insert in numerical order in the column headed “Purposes”: P16158

[30] Schedule 1, Part 1, entry for Empagliflozin with metformin in the form Tablet containing 5 mg empagliflozin with 1 g metformin hydrochloride [Maximum Quantity: 120; Number of Repeats: 5]

(a) insert in numerical order in the column headed “Circumstances”: C16162

(b) insert in numerical order in the column headed “Purposes”: P16162

[31] Schedule 1, Part 1, entry for Empagliflozin with metformin in the form Tablet containing 5 mg empagliflozin with 500 mg metformin hydrochloride [Maximum Quantity: 60; Number of Repeats: 5]

(a) insert in numerical order in the column headed “Circumstances”: C16158

(b) insert in numerical order in the column headed “Purposes”: P16158

[32] Schedule 1, Part 1, entry for Empagliflozin with metformin in the form Tablet containing 5 mg empagliflozin with 500 mg metformin hydrochloride [Maximum Quantity: 120; Number of Repeats: 5]

(a) insert in numerical order in the column headed “Circumstances”: C16162

(b) insert in numerical order in the column headed “Purposes”: P16162

[33] Schedule 1, Part 1, entry for Empagliflozin with metformin in the form Tablet containing 12.5 mg empagliflozin with 1 g metformin hydrochloride [Maximum Quantity: 60; Number of Repeats: 5]

(a) insert in numerical order in the column headed “Circumstances”: C16158

(b) insert in numerical order in the column headed “Purposes”: P16158

[34] Schedule 1, Part 1, entry for Empagliflozin with metformin in the form Tablet containing 12.5 mg empagliflozin with 1 g metformin hydrochloride [Maximum Quantity: 120; Number of Repeats: 5]

(a) insert in numerical order in the column headed “Circumstances”: C16162

(b) insert in numerical order in the column headed “Purposes”: P16162

[35] Schedule 1, Part 1, entry for Empagliflozin with metformin in the form Tablet containing 12.5 mg empagliflozin with 500 mg metformin hydrochloride [Maximum Quantity: 60; Number of Repeats: 5]

(a) insert in numerical order in the column headed “Circumstances”: C16158

(b) insert in numerical order in the column headed “Purposes”: P16158

[36] Schedule 1, Part 1, entry for Empagliflozin with metformin in the form Tablet containing 12.5 mg empagliflozin with 500 mg metformin hydrochloride [Maximum Quantity: 120; Number of Repeats: 5]

(a) insert in numerical order in the column headed “Circumstances”: C16162

(b) insert in numerical order in the column headed “Purposes”: P16162

[37] Schedule 1, Part 1, entry for Epirubicin

omit from the column headed “Manner of Administration”: Injection intravesical  substitute: Injection/intravesical

[38] Schedule 1, Part 1, after entry for Erlotinib in the form Tablet 25 mg (as hydrochloride) [Brand: Erlotinib APOTEX]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Erlotinib | Tablet 25 mg (as hydrochloride) | Oral | ERLOTINIB ARX | XT | MP | C4473 C4600 C7446 |  | 30 | 3 |  | 30 |  |  |

[39] Schedule 1, Part 1, entries for Estradiol

(a) omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Estradiol | Transdermal patches 585 micrograms, 24 (S19A) | Transdermal | Estramon 37.5 (Germany) | DZ | MP NP |  |  | 1 | 1 |  | 1 |  |  |

(b) omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Estradiol | Transdermal patches 780 micrograms, 24 (S19A) | Transdermal | Estramon 50 (Germany) | DZ | MP NP |  |  | 1 | 1 |  | 1 |  |  |

(c) omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Estradiol | Transdermal patches 1.17 mg, 24 (S19A) | Transdermal | Estramon 75 (Germany) | DZ | MP NP |  |  | 1 | 1 |  | 1 |  |  |

(d) omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Estradiol | Transdermal patches 1.56 mg, 24 (S19A) | Transdermal | Estramon 100 (Germany) | DZ | MP NP |  |  | 1 | 1 |  | 1 |  |  |

[40] Schedule 1, Part 1, after entry for Fingolimod in the form Capsule 500 micrograms (as hydrochloride) [Brand: AKM Fingolimod]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Fingolimod | Capsule 500 micrograms (as hydrochloride) | Oral | Fingolimod Dr.Reddy's | RZ | MP NP | C16301 C16323 |  | 28 | 5 |  | 28 |  |  |

[41] Schedule 1, Part 1, entry for Follitropin alfa with lutropin alfa

(a) omit from the column headed “Circumstances”: C5250 substitute: C16362

(b) omit from the column headed “Maximum Quantity”: 2 substitute: 4

[42] Schedule 1, Part 1, entries for Follitropin beta in the form Solution for injection 600 I.U. in 0.72 mL multi-dose cartridge

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Follitropin beta | Solution for injection 600 I.U. in 0.72 mL multi-dose cartridge | Injection | Recagon | OV | MP | C6257 C6321 | P6257 P6321 | 2 | 5 |  | 1 |  |  |
| Follitropin beta | Solution for injection 600 I.U. in 0.72 mL multi-dose cartridge | Injection | Recagon | OV | MP | C5027 | P5027 | 4 | 0 |  | 1 |  | C(100) |

[43] Schedule 1, Part 1, entry for Framycetin

omit from the column headed “Manner of Administration”: Application to the eye ear substitute: Application to the eye/ear

[44] Schedule 1, Part 1, entries for Glyceryl trinitrate

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Glyceryl trinitrate | Transdermal patch 36 mg | Transdermal | Minitran 10 | IL | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Glyceryl trinitrate | Transdermal patch 36 mg | Transdermal | Minitran 10 | IL | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

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

(a) omit from the column headed “Circumstances”: C9153

(b) insert in numerical order in the column headed “Circumstsances”: C16370

(c) omit from the column headed “Purposes”: P9153

(d) insert in numerical order in the column headed “Purposes”: P16370

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

(a) omit from the column headed “Circumstances”: C9153

(b) insert in numerical order in the column headed “Circumstances”: C16370

(c) omit from the column headed “Purposes”: P9153

(d) insert in numerical order in the column headed “Purposes”: P16370

[47] Schedule 1, Part 1, entries for Goserelin and bicalutamide

omit from the column headed “Manner of Administration” (all instances): Implantation oral  substitute (all instances): Implantation/oral

[48] Schedule 1, Part 1, entry for Hyaluronic acid in the form Eye drops containing sodium hyaluronate 1 mg per mL, 10 mL [Maximum Quantity: 1; Number of Repeats: 5]

(a) omit from the column headed “Circumstances”: C4105 substitute: C6172

(b) omit from the column headed “Purposes”: P4105 substitute: P6172

[49] Schedule 1, Part 1, entry for Hyaluronic acid in the form Eye drops containing sodium hyaluronate 2 mg per mL, 10 mL [Maximum Quantity: 1; Number of Repeats: 5]

(a) omit from the column headed “Circumstances”: C4105 substitute: C6172

(b) omit from the column headed “Purposes”: P4105 substitute: P6172

[50] Schedule 1, Part 1, entries for Hydrocortisone

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hydrocortisone | Rectal foam containing hydrocortisone acetate 90 mg per applicatorful, 14 applications, aerosol 21.1 g | Rectal | Colifoam | GO | MP NP | C4872 C4893 |  | 2 | 3 |  | 1 |  |  |

[51] Schedule 1, Part 1, entries for Insulin degludec with insulin aspart

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Insulin degludec with insulin aspart | Injections, pre-filled pen, 70 units-30 units per mL, 3 mL, 5 | Injection | Ryzodeg Flextouch | NO | MP NP |  |  | 5 | 1 |  | 1 |  |  |

[52] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 20 mg [Brand: Roaccutane]

omit from the column headed “Responsible Person”: RO substitute: PB

[53] Schedule 1, Part 1, omit entries for Ketoprofen

[54] Schedule 1, Part 1, entries for Lacosamide

(a) omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lacosamide | Tablet 50 mg | Oral | Lacoress | LR | MP NP | C8813 |  | 14 | 1 |  | 14 |  |  |

(b) omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lacosamide | Tablet 100 mg | Oral | Lacoress | LR | MP NP | C8813 | P8813 | 14 | 1 |  | 14 |  |  |
| Lacosamide | Tablet 100 mg | Oral | Lacoress | LR | MP NP | C8770 C8815 | P8770 P8815 | 56 | 5 |  | 56 |  |  |
| Lacosamide | Tablet 100 mg | Oral | Lacoress | LR | MP NP | C14857 | P14857 | 112 | 5 |  | 56 |  |  |

(c) omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lacosamide | Tablet 150 mg | Oral | Lacoress | LR | MP NP | C8813 | P8813 | 14 | 1 |  | 14 |  |  |
| Lacosamide | Tablet 150 mg | Oral | Lacoress | LR | MP NP | C8770 C8815 | P8770 P8815 | 56 | 5 |  | 56 |  |  |
| Lacosamide | Tablet 150 mg | Oral | Lacoress | LR | MP NP | C14857 | P14857 | 112 | 5 |  | 56 |  |  |

(d) omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lacosamide | Tablet 200 mg | Oral | Lacoress | LR | MP NP | C8770 C8815 | P8770 P8815 | 56 | 5 |  | 56 |  |  |
| Lacosamide | Tablet 200 mg | Oral | Lacoress | LR | MP NP | C14857 | P14857 | 112 | 5 |  | 56 |  |  |

[55] Schedule 1, Part 1, entries for Lenalidomide

(a) omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lenalidomide | Capsule 5 mg | Oral | Lenalidomide-Teva | TB | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 14 |  | D(100) |
| Lenalidomide | Capsule 5 mg | Oral | Lenalidomide-Teva | TB | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 21 |  | D(100) |
| Lenalidomide | Capsule 5 mg | Oral | Lenalidomide-Teva | TB | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 28 |  | D(100) |

(b) omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lenalidomide | Capsule 10 mg | Oral | Lenalidomide-Teva | TB | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 14 |  | D(100) |
| Lenalidomide | Capsule 10 mg | Oral | Lenalidomide-Teva | TB | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 21 |  | D(100) |
| Lenalidomide | Capsule 10 mg | Oral | Lenalidomide-Teva | TB | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 28 |  | D(100) |

(c) omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lenalidomide | Capsule 15 mg | Oral | Lenalidomide-Teva | TB | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 14 |  | D(100) |
| Lenalidomide | Capsule 15 mg | Oral | Lenalidomide-Teva | TB | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 21 |  | D(100) |
| Lenalidomide | Capsule 15 mg | Oral | Lenalidomide-Teva | TB | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 28 |  | D(100) |

(d) omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lenalidomide | Capsule 25 mg | Oral | Lenalidomide-Teva | TB | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 14 |  | D(100) |
| Lenalidomide | Capsule 25 mg | Oral | Lenalidomide-Teva | TB | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 21 |  | D(100) |

[56] Schedule 1, Part 1, entries for Leuprorelin and bicalutamide

omit from the column headed “Manner of Administration” (all instances): Injection oral substitute (all instances): Injection/oral

[57] Schedule 1, Part 1, entries for Levodopa with carbidopa in the form Intestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg per mL, 100 mL

omit from the column headed “Manner of Administration” (all instances): Intra intestinal substitute (all instances): Intra-intestinal

[58] Schedule 1, Part 1, entries for Medroxyprogesterone

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Medroxyprogesterone | Tablet containing medroxyprogesterone acetate 500 mg | Oral | Provera | PF | MP | C5731 | P5731 | 30 | 2 |  | 30 |  |  |
| Medroxyprogesterone | Tablet containing medroxyprogesterone acetate 500 mg | Oral | Provera | PF | MP | C15007 | P15007 | 60 | 2 |  | 30 |  |  |

[59] Schedule 1, Part 1, after entry for Methylprednisolone in the form Fatty ointment containing methylprednisolone aceponate 1 mg per g, 15 g [Brand: Advantan (Fatty); Maximum Quantity: 10; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Methylprednisolone | Fatty ointment containing methylprednisolone aceponate 1 mg per g, 15 g | Application | Metvant (Fatty) | NB | MP NP | C4957 | P4957 | 1 | 0 |  | 1 |  |  |
| Methylprednisolone | Fatty ointment containing methylprednisolone aceponate 1 mg per g, 15 g | Application | Metvant (Fatty) | NB | MP NP | C6232 | P6232 | 2 | 5 |  | 1 |  |  |
| Methylprednisolone | Fatty ointment containing methylprednisolone aceponate 1 mg per g, 15 g | Application | Metvant (Fatty) | NB | MP NP | C6246 | P6246 | 4 | 5 |  | 1 |  |  |
| Methylprednisolone | Fatty ointment containing methylprednisolone aceponate 1 mg per g, 15 g | Application | Metvant (Fatty) | NB | MP NP | C6218 | P6218 | 6 | 5 |  | 1 |  |  |
| Methylprednisolone | Fatty ointment containing methylprednisolone aceponate 1 mg per g, 15 g | Application | Metvant (Fatty) | NB | MP NP | C6263 | P6263 | 8 | 5 |  | 1 |  |  |
| Methylprednisolone | Fatty ointment containing methylprednisolone aceponate 1 mg per g, 15 g | Application | Metvant (Fatty) | NB | MP NP | C6231 | P6231 | 10 | 5 |  | 1 |  |  |

[60] Schedule 1, Part 1, after entry for Methylprednisolone in the form Ointment containing methylprednisolone aceponate 1 mg per g, 15 g [Brand: Advantan; Maximum Quantity: 10; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Methylprednisolone | Ointment containing methylprednisolone aceponate 1 mg per g, 15 g | Application | Metvant | NB | MP NP | C4957 | P4957 | 1 | 0 |  | 1 |  |  |
| Methylprednisolone | Ointment containing methylprednisolone aceponate 1 mg per g, 15 g | Application | Metvant | NB | MP NP | C6232 | P6232 | 2 | 5 |  | 1 |  |  |
| Methylprednisolone | Ointment containing methylprednisolone aceponate 1 mg per g, 15 g | Application | Metvant | NB | MP NP | C6246 | P6246 | 4 | 5 |  | 1 |  |  |
| Methylprednisolone | Ointment containing methylprednisolone aceponate 1 mg per g, 15 g | Application | Metvant | NB | MP NP | C6218 | P6218 | 6 | 5 |  | 1 |  |  |
| Methylprednisolone | Ointment containing methylprednisolone aceponate 1 mg per g, 15 g | Application | Metvant | NB | MP NP | C6263 | P6263 | 8 | 5 |  | 1 |  |  |
| Methylprednisolone | Ointment containing methylprednisolone aceponate 1 mg per g, 15 g | Application | Metvant | NB | MP NP | C6231 | P6231 | 10 | 5 |  | 1 |  |  |

[61] Schedule 1, Part 1, after entry for Molnupiravir

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Momelotinib | Tablet 100 mg (as dihydrochloride monohydrate) | Oral | Omjjara | GK | MP | C16363 C16390 | P16363 P16390 | 30 | 0 |  | 30 |  |  |
| Momelotinib | Tablet 100 mg (as dihydrochloride monohydrate) | Oral | Omjjara | GK | MP | C16367 C16373 | P16367 P16373 | 30 | 5 |  | 30 |  |  |
| Momelotinib | Tablet 150 mg (as dihydrochloride monohydrate) | Oral | Omjjara | GK | MP | C16363 C16390 | P16363 P16390 | 30 | 0 |  | 30 |  |  |
| Momelotinib | Tablet 150 mg (as dihydrochloride monohydrate) | Oral | Omjjara | GK | MP | C16367 C16373 | P16367 P16373 | 30 | 5 |  | 30 |  |  |
| Momelotinib | Tablet 200 mg (as dihydrochloride monohydrate) | Oral | Omjjara | GK | MP | C16363 C16390 | P16363 P16390 | 30 | 0 |  | 30 |  |  |
| Momelotinib | Tablet 200 mg (as dihydrochloride monohydrate) | Oral | Omjjara | GK | MP | C16367 C16373 | P16367 P16373 | 30 | 5 |  | 30 |  |  |

[62] Schedule 1, Part 1, entries for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg

omit:

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

[63] Schedule 1, Part 1, entries for Nevirapine

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Nevirapine | Tablet 400 mg (extended release) | Oral | Viramune XR | BY | MP NP | C4454 C4526 |  | 60 | 5 |  | 30 |  | D(100) |

[64] Schedule 1, Part 1, entries for Olanzapine in the form Tablet 7.5 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Olanzapine | Tablet 7.5 mg | Oral | Olanzapine APOTEX | GX | MP NP | C4246 C5869 |  | 28 | 5 |  | 28 |  |  |

[65] Schedule 1, Part 1, entry for Omeprazole in the form Tablet 20 mg [Brand: APO-Omeprazole; Authorised Prescriber: MP NP MW]

omit from the column headed “Authorised Prescriber”: MP NP MW substitute: MP MW NP

[66] Schedule 1, Part 1, entry for Omeprazole in the form Tablet 20 mg [Brand: Maxor EC Tabs; Authorised Prescriber: MP NP MW]

omit from the column headed “Authorised Prescriber”: MP NP MW substitute: MP MW NP

[67] Schedule 1, Part 1, after entry for Omeprazole in the form Tablet 20 mg [Brand: Maxor EC Tabs; Maximum Quantity: 120; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Omeprazole | Tablet 20 mg | Oral | OMEPRAZOLE-WGR | WG | MP MW NP | C8774 | P8774 | 30 | 1 |  | 30 |  |  |
| Omeprazole | Tablet 20 mg | Oral | OMEPRAZOLE-WGR | WG | MP NP | C8775 | P8775 | 30 | 1 |  | 30 |  |  |
| Omeprazole | Tablet 20 mg | Oral | OMEPRAZOLE-WGR | WG | MP NP | C8776 C8780 C8866 | P8776 P8780 P8866 | 30 | 5 |  | 30 |  |  |
| Omeprazole | Tablet 20 mg | Oral | OMEPRAZOLE-WGR | WG | MP NP | C15530 C15658 C15678 | P15530 P15658 P15678 | 60 | 5 |  | 30 |  |  |
| Omeprazole | Tablet 20 mg | Oral | OMEPRAZOLE-WGR | WG | MP | C11310 | P11310 | 60 | 5 |  | 30 |  |  |
| Omeprazole | Tablet 20 mg | Oral | OMEPRAZOLE-WGR | WG | MP | C15856 | P15856 | 120 | 5 |  | 30 |  |  |

[68] Schedule 1, Part 1, entry for Omeprazole in the form Tablet 20 mg [Brand: Ozmep; Authorised Prescriber: MP NP MW]

omit from the column headed “Authorised Prescriber”: MP NP MW substitute: MP MW NP

[69] Schedule 1, Part 1, entries for Palonosetron

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Palonosetron | Injection 250 micrograms (as hydrochloride) in 5 mL | Injection | Aloxi | JZ | MP NP | C5686 |  | 1 | 0 |  | 1 |  |  |
| Palonosetron | Injection 250 micrograms (as hydrochloride) in 5 mL | Injection | Aloxi | JZ | MP | C5805 |  | 1 | 0 |  | 1 |  | C(100) |

[70] Schedule 1, Part 1, entries for Paracetamol

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Paracetamol | Oral liquid 120 mg per 5 mL, 100 mL | Oral | Panamax | SW | PDP | C5846 | P5846 | 1 | 0 |  | 1 |  |  |
| Paracetamol | Oral liquid 120 mg per 5 mL, 100 mL | Oral | Panamax | SW | MP NP | C5835 | P5835 | 1 | 2 |  | 1 |  |  |

[71] Schedule 1, Part 1, entry for Phytomenadione

omit from the column headed “Manner of Administration”: Injection oral substitute: Injection/oral

[72] Schedule 1, Part 1, after entry for Pioglitazone in the form Tablet 45 mg (as hydrochloride) [Brand: Vexazone; Maximum Quantity: 56; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pirfenidone | Tablet 801 mg | Oral | ARX-Pirfenidone | XW | MP | C13380 |  | 90 | 5 |  | 90 |  |  |

[73] Schedule 1, Part 1, entries for Piroxicam

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Piroxicam | Dispersible tablet 20 mg | Oral | Feldene-D | PF | PDP | C6214 | P6214 | 25 | 0 |  | 25 |  |  |
| Piroxicam | Dispersible tablet 20 mg | Oral | Feldene-D | PF | MP NP | C6214 | P6214 | 25 | 3 |  | 25 |  |  |

[74] Schedule 1, Part 1, after entry for Propranolol in the form Tablet containing propranolol hydrochloride 40 mg [Brand: PROPRANOLOL-WGR; Maximum Quantity: 200; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Propylene glycol | Eye drops 60 micrograms per mL, 10 mL | Application to the eye | Systane Balance | AQ | AO MP NP | C16387 |  | 1 | 5 |  | 1 |  |  |

[75] Schedule 1, Part 1, entries for Quetiapine

(a) omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Quetiapine | Tablet 25 mg (as fumarate) | Oral | Quetiapine APOTEX | GX | MP NP | C4246 C5869 C7927 |  | 60 | 0 |  | 60 |  |  |

(b) omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Quetiapine | Tablet 200 mg (as fumarate) | Oral | Quetiapine APOTEX | GX | MP NP | C4246 C5611 C5869 |  | 60 | 5 |  | 60 |  |  |

(c) omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Quetiapine | Tablet 300 mg (as fumarate) | Oral | Quetiapine APOTEX | GX | MP NP | C4246 C5611 C5869 |  | 60 | 5 |  | 60 |  |  |

[76] Schedule 1, Part 1, entries for Ramipril with felodipine

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ramipril with felodipine | Tablet 2.5 mg-2.5 mg (modified release) | Oral | Triasyn 2.5/2.5 | SW | MP NP | C4398 | P4398 | 30 | 5 |  | 30 |  |  |
| Ramipril with felodipine | Tablet 2.5 mg-2.5 mg (modified release) | Oral | Triasyn 2.5/2.5 | SW | MP NP | C14245 | P14245 | 60 | 5 |  | 30 |  |  |

[77] Schedule 1, Part 1, entry for Risankizumab in the form Injection 150 mg in 1 mL pre-filled pen [Maximum Quantity: 1; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C16305

(b) insert in numerical order in the column headed “Circumstances”: C16391

(c) omit from the column headed “Purposes”: P16305

(d) insert in numerical order in the column headed “Purposes”: P16391

[78] Schedule 1, Part 1, after entry for Rituximab in the form Solution for I.V. infusion 500 mg in 50 mL [Brand: Truxima; Maximum Quantity: See Note 3; Number of Repeats: See Note 3]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Rivaroxaban | Tablet 2.5 mg | Oral | Rivaroxaban Lupin | GQ | MP NP | C10992 | P10992 | 60 | 5 |  | 60 |  |  |
| Rivaroxaban | Tablet 2.5 mg | Oral | Rivaroxaban Lupin | GQ | MP | C11013 | P11013 | 60 | 5 |  | 60 |  |  |
| Rivaroxaban | Tablet 2.5 mg | Oral | Rivaroxaban Lupin | GQ | MP NP | C14298 | P14298 | 120 | 5 |  | 60 |  |  |

[79] Schedule 1, Part 1, after entry for Rivaroxaban in the form Tablet 10 mg [Brand: Rivaroxaban Dr.Reddy's; Maximum Quantity: 60; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Rivaroxaban | Tablet 10 mg | Oral | Rivaroxaban Lupin | GQ | MP NP | C4402 | P4402 | 30 | 0 |  | 30 |  |  |
| Rivaroxaban | Tablet 10 mg | Oral | Rivaroxaban Lupin | GQ | MP NP | C4132 | P4132 | 30 | 5 |  | 30 |  |  |
| Rivaroxaban | Tablet 10 mg | Oral | Rivaroxaban Lupin | GQ | MP NP | C14300 | P14300 | 60 | 5 |  | 30 |  |  |

[80] Schedule 1, Part 1, after entry for Rivaroxaban in the form Tablet 15 mg [Brand: Rivaroxaban Dr.Reddy's; Maximum Quantity: 56; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Rivaroxaban | Tablet 15 mg | Oral | Rivaroxaban Lupin | GQ | MP NP | C4269 | P4269 | 28 | 5 |  | 28 |  |  |
| Rivaroxaban | Tablet 15 mg | Oral | Rivaroxaban Lupin | GQ | MP NP | C4098 C5098 | P4098 P5098 | 42 | 0 |  | 42 |  |  |
| Rivaroxaban | Tablet 15 mg | Oral | Rivaroxaban Lupin | GQ | MP NP | C14301 | P14301 | 56 | 5 |  | 28 |  |  |

[81] Schedule 1, Part 1, after entry for Rivaroxaban in the form Tablet 20 mg [Brand: Rivaroxaban Dr.Reddy's; Maximum Quantity: 56; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Rivaroxaban | Tablet 20 mg | Oral | Rivaroxaban Lupin | GQ | MP NP | C4099 C4132 C4268 C4269 | P4099 P4132 P4268 P4269 | 28 | 5 |  | 28 |  |  |
| Rivaroxaban | Tablet 20 mg | Oral | Rivaroxaban Lupin | GQ | MP NP | C14264 C14300 C14301 C14318 | P14264 P14300 P14301 P14318 | 56 | 5 |  | 28 |  |  |

[82] Schedule 1, Part 1, entries for Ruxolitinib

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 | C16364 C16365 | P16364 P16365 | 112 | 0 |  | 56 |  |  |
| Ruxolitinib | Tablet 5 mg | Oral | Jakavi | NV | MP | C16367 C16373 | P16367 P16373 | 112 | 5 |  | 56 |  |  |
| Ruxolitinib | Tablet 10 mg | Oral | Jakavi | NV | MP | C16364 C16365 | P16364 P16365 | 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 | C13867 C13906 C16367 C16373 | P13867 P13906 P16367 P16373 | 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 | C16364 C16365 | P16364 P16365 | 56 | 0 |  | 56 |  |  |
| Ruxolitinib | Tablet 15 mg | Oral | Jakavi | NV | MP | C16367 C16373 | P16367 P16373 | 56 | 5 |  | 56 |  |  |
| Ruxolitinib | Tablet 20 mg | Oral | Jakavi | NV | MP | C16364 C16365 | P16364 P16365 | 56 | 0 |  | 56 |  |  |
| Ruxolitinib | Tablet 20 mg | Oral | Jakavi | NV | MP | C16367 C16373 | P16367 P16373 | 56 | 5 |  | 56 |  |  |

[83] Schedule 1, Part 1, entries for Sacubitril with valsartan

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sacubitril with valsartan | Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg | Oral | Entresto | NV | MP NP | C11680 | P11680 | 56 | 5 |  | 56 |  |  |
| Sacubitril with valsartan | Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg | Oral | Entresto | NV | MP NP | C14254 | P14254 | 112 | 5 |  | 56 |  |  |
| Sacubitril with valsartan | Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg | Oral | Pharmacor Sacubitril/Valsartan | CR | MP NP | C11680 | P11680 | 56 | 5 |  | 56 |  |  |
| Sacubitril with valsartan | Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg | Oral | Pharmacor Sacubitril/Valsartan | CR | MP NP | C14254 | P14254 | 112 | 5 |  | 56 |  |  |
| Sacubitril with valsartan | Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg | Oral | Valtresto | RM | MP NP | C11680 | P11680 | 56 | 5 |  | 56 |  |  |
| Sacubitril with valsartan | Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg | Oral | Valtresto | RM | MP NP | C14254 | P14254 | 112 | 5 |  | 56 |  |  |
| Sacubitril with valsartan | Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg | Oral | Entresto | NV | MP NP | C11680 | P11680 | 56 | 5 |  | 56 |  |  |
| Sacubitril with valsartan | Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg | Oral | Entresto | NV | MP NP | C14254 | P14254 | 112 | 5 |  | 56 |  |  |
| Sacubitril with valsartan | Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg | Oral | Pharmacor Sacubitril/Valsartan | CR | MP NP | C11680 | P11680 | 56 | 5 |  | 56 |  |  |
| Sacubitril with valsartan | Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg | Oral | Pharmacor Sacubitril/Valsartan | CR | MP NP | C14254 | P14254 | 112 | 5 |  | 56 |  |  |
| Sacubitril with valsartan | Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg | Oral | Valtresto | RM | MP NP | C11680 | P11680 | 56 | 5 |  | 56 |  |  |
| Sacubitril with valsartan | Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg | Oral | Valtresto | RM | MP NP | C14254 | P14254 | 112 | 5 |  | 56 |  |  |
| Sacubitril with valsartan | Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg | Oral | Entresto | NV | MP NP | C11680 | P11680 | 56 | 5 |  | 56 |  |  |
| Sacubitril with valsartan | Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg | Oral | Entresto | NV | MP NP | C14254 | P14254 | 112 | 5 |  | 56 |  |  |
| Sacubitril with valsartan | Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg | Oral | Pharmacor Sacubitril/Valsartan | CR | MP NP | C11680 | P11680 | 56 | 5 |  | 56 |  |  |
| Sacubitril with valsartan | Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg | Oral | Pharmacor Sacubitril/Valsartan | CR | MP NP | C14254 | P14254 | 112 | 5 |  | 56 |  |  |
| Sacubitril with valsartan | Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg | Oral | Valtresto | RM | MP NP | C11680 | P11680 | 56 | 5 |  | 56 |  |  |
| Sacubitril with valsartan | Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg | Oral | Valtresto | RM | MP NP | C14254 | P14254 | 112 | 5 |  | 56 |  |  |

[84] Schedule 1, Part 1, entries for Salbutamol

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Salbutamol | Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 20 (S19A) | Inhalation | pms-SALBUTAMOL | DZ | MP NP | C6815 C6825 |  | 3 | 5 |  | 1 |  |  |

[85] Schedule 1, Part 1, entry for Secukinumab in the form Injection 150 mg in 1 mL pre-filled pen [Maximum Quantity: 4; Number of Repeats: 0]

(a) omit from the column headed “Circumstances”: C9078

(b) insert in numerical order in the column headed “Circumstances”: C16382

(c) omit from the column headed “Purposes”: P9078

(d) insert in numerical order in the column headed “Purposes”: P16382

[86] Schedule 1, Part 1, entry for Secukinumab in the form Injection 150 mg in 1 mL pre-filled pen [Maximum Quantity: 8; Number of Repeats: 0]

(a) omit from the column headed “Circumstances”: C9078

(b) insert in numerical order in the column headed “Circumstances”: C16382

(c) omit from the column headed “Purposes”: P9078

(d) insert in numerical order in the column headed “Purposes”: P16382

[87] Schedule 1, Part 1, entries for Tenofovir with emtricitabine in the form Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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) |

[88] Schedule 1, Part 1, after entry for Tirofiban [Brand: Tirofiban Juno]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Tislelizumab | Solution concentrate for I.V. infusion 100 mg in 10 mL | Injection | Tevimbra | IE | MP | C16375 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

[89] Schedule 1, Part 1, entry for Tofacitinib in the form Tablet 5 mg [Maximum Quantity: 56; Number of Repeats: 3]

(a) omit from the column headed “Circumstances”: C11945

(b) insert in numerical order in the column headed “Circumstances”: C16392

(c) omit from the column headed “Purposes”: P11945

(d) insert in numerical order in the column headed “Purposes”: P16392

[90] Schedule 1, Part 1, after entry for Tolvaptan in the form Pack containing 28 tablets 15 mg and 28 tablets 45 mg

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Tolvaptan | Pack containing 28 tablets 15 mg and 28 tablets 45 mg | Oral | Tolvaptan Lupin | GQ | MP | C8288 C10250 |  | 1 | 5 |  | 1 |  |  |

[91] Schedule 1, Part 1, after entry for Tolvaptan in the form Pack containing 28 tablets 30 mg and 28 tablets 60 mg

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Tolvaptan | Pack containing 28 tablets 30 mg and 28 tablets 60 mg | Oral | Tolvaptan Lupin | GQ | MP | C8288 C10250 |  | 1 | 5 |  | 1 |  |  |

[92] Schedule 1, Part 1, after entry for Tolvaptan in the form Pack containing 28 tablets 30 mg and 28 tablets 90 mg

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Tolvaptan | Pack containing 28 tablets 30 mg and 28 tablets 90 mg | Oral | Tolvaptan Lupin | GQ | MP | C8288 C10250 |  | 1 | 5 |  | 1 |  |  |

[93] Schedule 1, Part 1, after entry for Tramadol in the form Tablet (sustained release) containing tramadol hydrochloride 200 mg *[Brand: Zydol SR 200]*

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Trametinib | Powder for oral solution 50 micrograms per mL (as dimethylsulfoxide), 90 mL | Oral | Mekinist | NV | MP | C16371 C16372 |  | 13 | 3 |  | 1 |  |  |

[94] Schedule 1, Part 1, after entry for Trametinib in the form Tablet 500 micrograms [Maximum Quantity: 90; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Trametinib | Tablet 500 micrograms | Oral | Mekinist | NV | MP | C16371 C16372 | P16371 P16372 | 120 | 3 |  | 30 |  |  |

[95] Schedule 1, Part 1, entry for Trametinib in the form Tablet 2 mg [Maximum Quantity: 30; Number of Repeats: 3]

(a) insert in numerical order in the column headed “Circumstances”: C16371 C16372

(b) insert in numerical order in the column headed “Purposes”: P16371 P16372

[96] Schedule 1, Part 1, entries for Trastuzumab in the form Powder for I.V. infusion 150 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Trastuzumab | Powder for I.V. infusion 150 mg | Injection | Kanjinti | JU | MP | C9349 C9353 C9571 C9573 C10213 C10294 C15820 C15831 |  | See Note 3 | See Note 3 | V15820 V15831 | 1 |  | PB(100) |

[97] Schedule 1, Part 1, entry for Upadacitinib in the form Tablet 15 mg [Maximum Quantity: 28; Number of Repeats: 3]

(a) omit from the column headed “Circumstances”: C11945

(b) insert in numerical order in the column headed “Circumstances”: C16392

(c) omit from the column headed “Purposes”: P11945

(d) insert in numerical order in the column headed “Purposes”: P16392

[98] Schedule 1, Part 2

insert as first entry:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Adefovir | Tablet containing adefovir dipivoxil 10 mg | Oral | APO-Adefovir | TX | 30 |  | D(100) |

[99] Schedule 1, Part 2, after entry for Evolocumab

insert:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Glyceryl trinitrate | Transdermal patch 36 mg | Transdermal | Minitran 10 | IL | 30 |  |  |

[100] Schedule 1, Part 2, after entry for Hypromellose with carbomer 980 [Brand: HPMC PAA]

insert:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Ketoprofen | Capsule 200 mg (sustained release) | Oral | Orudis SR 200 | SW | 28 |  |  |
| Nevirapine | Tablet 400 mg (extended release) | Oral | Viramune XR | BY | 30 |  | D(100) |
| Paracetamol | Oral liquid 120 mg per 5 mL, 100 mL | Oral | Panamax | SW | 1 |  |  |

[101] Schedule 1, Part 2, after entry for Protein hydrolysate formula with medium chain triglycerides

insert:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Ramipril with felodipine | Tablet 2.5 mg-2.5 mg (modified release) | Oral | Triasyn 2.5/2.5 | SW | 30 |  |  |

[102] Schedule 3, after entry for Responsible Person code RJ

insert:

|  |  |  |
| --- | --- | --- |
| RM | Pharmacor Pty Limited | 58 121 020 835 |

[103] Schedule 4, Part 1, omit entry for Circumstances Code “C4105”

[104] Schedule 4, Part 1, omit entry for Circumstances Code “C4526”

[105] Schedule 4, Part 1, entry for Circumstances Code “C4872”

omit from the column headed “Listed Drug”: Hydrocortisone

[106] Schedule 4, Part 1, entry for Circumstances Code “C4893”

omit from the column headed “Listed Drug”: Hydrocortisone

[107] Schedule 4, Part 1, omit entry for Circumstances Code “C5250”

[108] Schedule 4, Part 1, omit entry for Circumstances Code “C5731”

[109] Schedule 4, Part 1, entry for Circumstances Code “C5970”

insert in the column headed “Listed Drug” after the entry for “Amino acid formula with fat, carbohydrate without phenylalanine”: Amino acid formula with fat, carbohydrate, vitamins and minerals without phenylalanine

[110] Schedule 4, Part 1, entry for Circumstances Code “C6172”

insert in alphabetical order in the column headed “Listed Drug”: Hyaluronic acid

[111] Schedule 4, Part 1, entry for Circumstances Code “C6214”

omit from the column headed “Listed Drug”: Ketoprofen

[112] Schedule 4, Part 1, omit entry for Circumstances Code “C9078”

[113] Schedule 4, Part 1, omit entry for Circumstances Code “C9153”

[114] Schedule 4, Part 1, omit entry for Circumstances Code “C11945”

[115] Schedule 4, Part 1, omit entry for Circumstances Code “C12140”

[116] Schedule 4, Part 1, omit entry for Circumstances Code “C12842”

[117] Schedule 4, Part 1, omit entry for Circumstances Code “C13127”

[118] Schedule 4, Part 1, omit entry for Circumstances Code “C13128”

[119] Schedule 4, Part 1, omit entry for Circumstances Code “C13130”

[120] Schedule 4, Part 1, omit entry for Circumstances Code “C13173”

[121] Schedule 4, Part 1, omit entry for Circumstances Code “C15007”

[122] Schedule 4, Part 1, omit entry for Circumstances Code “C15950”

[123] Schedule 4, Part 1, entry for Circumstances Code “C16158”

insert in alphabetical order in the column headed “Listed Drug”: Empagliflozin with metformin

[124] Schedule 4, Part 1, entry for Circumstances Code “C16162”

insert in alphabetical order in the column headed “Listed Drug”: Empagliflozin with metformin

[125] Schedule 4, Part 1, entry for Circumstances Code “C16164”

insert in alphabetical order in the column headed “Listed Drug”: Empagliflozin

[126] Schedule 4, Part 1, entry for Circumstances Code “C16220”

insert in alphabetical order in the column headed “Listed Drug”: Empagliflozin

[127] Schedule 4, Part 1, omit entry for Circumstances Code “C16305”

[128] Schedule 4, Part 1, after entry for Circumstances Code “C16356”

insert:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C16358 | P16358 | CN16358 | Dabrafenib | Paediatric low grade glioma  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have either: (i) stable, (ii) responding disease based on the Response Assessment in Neuro-Oncology (RANO) criteria; AND  Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition. | Compliance with Authority Required procedures |
| C16360 | P16360 | CN16360 | Dabrafenib | Paediatric low grade glioma  Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements  Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2025; AND  The condition must have been World Health Organisation (WHO) grade 1 or 2 prior to commencing treatment with this therapy; AND  The condition must have progressed following surgical excision prior to commencing treatment with this therapy; or  The condition must not have been amenable to surgery with risk of neurological impairment following progression prior to commencing treatment with this therapy; AND  The condition must be positive for a BRAF V600 mutation; AND  Patient must have had either a: (i) Karnofsky, (ii) Lansky performance score of at least 50% prior to commencing treatment with this therapy; AND  Patient must have either: (i) stable, (ii) responding disease based on the Response Assessment in Neuro-Oncology (RANO) criteria; AND  Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition.  Patient must have been aged between 12 months to 18 years prior to commencing treatment with this therapy. | Compliance with Authority Required procedures |
| C16362 | P16362 | CN16362 | Follitropin alfa with lutropin alfa | Stimulation of follicular development  Patient must have severe LH deficiency; AND  Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule. | Compliance with Authority Required procedures - Streamlined Authority Code 16362 |
| C16363 | P16363 | CN16363 | Momelotinib | High risk and intermediate-2 risk myelofibrosis  Initial treatment  The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report; AND  Patient must have a haemoglobin level of less than 100 g per L prior to commencing treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.  Details of the following must be documented in the patient's medical records:  (a) the bone marrow biopsy report confirming diagnosis of myelofibrosis (date, unique identifying number/code or provider number); and  (b) a classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS. | Compliance with Authority Required procedures |
| C16364 | P16364 | CN16364 | Ruxolitinib | High risk and intermediate-2 risk myelofibrosis  Initial treatment  The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report; AND  The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.  Details of the following must be documented in the patient's medical records:  (a) the bone marrow biopsy report confirming diagnosis of myelofibrosis (date, unique identifying number/code or provider number); and  (b) a classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS. | Compliance with Authority Required procedures |
| C16365 | P16365 | CN16365 | Ruxolitinib | Intermediate-1 risk myelofibrosis  Initial treatment  The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report; AND  Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy; or  Patient must have intolerance to prior treatment with a JAK inhibitor for this condition; AND  The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.  Details of the following must be documented in the patient's medical records:  (a) the bone marrow biopsy report confirming diagnosis of myelofibrosis (date, unique identifying number/code or provider number); and  (b) a classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS. | Compliance with Authority Required procedures |
| C16367 | P16367 | CN16367 | Momelotinib  Ruxolitinib | High risk and intermediate-2 risk myelofibrosis  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 16367 |
| C16370 | P16370 | CN16370 | Golimumab | 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.  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:  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.  An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-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 |
| C16371 | P16371 | CN16371 | Trametinib | Paediatric high grade glioma  Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition. | Compliance with Authority Required procedures |
| C16372 | P16372 | CN16372 | Trametinib | Paediatric low grade glioma  Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition. | Compliance with Authority Required procedures |
| C16373 | P16373 | CN16373 | Momelotinib  Ruxolitinib | Intermediate-1 risk myelofibrosis  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 16373 |
| C16375 | P16375 | CN16375 | Tislelizumab | Advanced or metastatic gastro-oesophageal cancer  Patient must be untreated (up until initiating this drug) with programmed cell death-1/ligand-1 (PD-1/PD-L1) inhibitor therapy for gastro-oesophageal cancer; AND  Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1.  Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first: (i) disease progression despite treatment with this drug, (ii) 24 months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs. | Compliance with Authority Required procedures - Streamlined Authority Code 16375 |
| C16377 | P16377 | CN16377 | Dabrafenib | Paediatric low grade glioma  Initial treatment  The condition must be World Health Organisation (WHO) grade 1 or 2; AND  The condition must have progressed following surgical excision; or  The condition must not be amenable to surgery with risk of neurological impairment following progression; AND  The condition must be positive for a BRAF V600 mutation; AND  Patient must have either a: (i) Karnofsky, (ii) Lansky performance score of at least 50%; AND  Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition.  Patient must have been aged between 12 months to 18 years at diagnosis. | Compliance with Authority Required procedures |
| C16378 | P16378 | CN16378 | Dabrafenib | Paediatric high grade glioma  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have either: (i) stable, (ii) responding disease based on the Response Assessment in Neuro-Oncology (RANO) criteria; AND  Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition. | Compliance with Authority Required procedures |
| C16382 | P16382 | CN16382 | Secukinumab | 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.  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(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.  An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-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 |
| C16385 | P16385 | CN16385 | Dabrafenib | Paediatric high grade glioma  Initial treatment  The condition must be World Health Organisation (WHO) grade 3 or 4; AND  The condition must be positive for a BRAF V600 mutation; AND  Patient must have either a: (i) Karnofsky, (ii) Lansky performance score of at least 50%; AND  Patient must have relapsed or progressed following frontline therapy; or  Patient must have failed to respond to frontline therapy; AND  Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition.  Patient must have been aged between 12 months to 18 years at diagnosis. | Compliance with Authority Required procedures |
| C16387 | P16387 | CN16387 | Propylene glycol | Severe dry eye syndrome |  |
| C16389 | P16389 | CN16389 | Dabrafenib | Paediatric high grade glioma  Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements  Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2025; AND  The condition must have been World Health Organisation (WHO) grade 3 or 4 prior to commencing treatment with this therapy; AND  Patient must have relapsed or progressed following frontline therapy prior to commencing treatment with this therapy; or  Patient must have failed to respond to frontline therapy prior to commencing treatment with this therapy; AND  The condition must be positive for a BRAF V600 mutation; AND  Patient must have had either a: (i) Karnofsky, (ii) Lansky performance score of at least 50% prior to commencing treatment with this therapy; AND  Patient must have either: (i) stable, (ii) responding disease based on the Response Assessment in Neuro-Oncology (RANO) criteria; AND  Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition.  Patient must have been aged between 12 months to 18 years prior to commencing treatment with this therapy. | Compliance with Authority Required procedures |
| C16390 | P16390 | CN16390 | Momelotinib | Intermediate-1 risk myelofibrosis  Initial treatment  The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report; AND  Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy; or  Patient must have intolerance to prior treatment with a JAK inhibitor for this condition; AND  Patient must have a haemoglobin level of less than 100 g per L prior to commencing treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.  Details of the following must be documented in the patient's medical records:  (a) the bone marrow biopsy report confirming diagnosis of myelofibrosis (date, unique identifying number/code or provider number); and  (b) a classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS. | Compliance with Authority Required procedures |
| C16391 | P16391 | CN16391 | Risankizumab | Severe psoriatic arthritis  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 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 28 weeks of treatment under this restriction.  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.  Patient must be at least 18 years of age.  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) details of the proposed prescription; 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 |
| C16392 | P16392 | CN16392 | Tofacitinib  Upadacitinib | 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.  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 |
| C16396 | P16396 | CN16396 | Bimekizumab | Severe psoriatic arthritis  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 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.  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.  Patient must be at least 18 years of age.  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) details of the proposed prescription; 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 |

[129] Schedule 5, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe

insert in the column headed “Brand” after entry for the Brand “Humira”: Hyrimoz

[130] Schedule 5, entry for Aripiprazole in each of the forms: Tablet 15 mg; Tablet 30 mg; and Tablet 20 mg

omit from the column headed “Brand”: Aripic Aripiprazole

[131] Schedule 5, entries for Clonazepam

omit:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Clonazepam | GRP-29271 | Tablet 2 mg | Oral | Paxam 2 |
| Clonazepam | GRP-29271 | Tablet 2 mg (S19A) | Oral | Clonazepam USP (Advagen Pharma, USA) |

[132] Schedule 5, entry for Clopidogrel with aspirin

omit from the column headed “Brand”: Clopidogrel Winthrop plus aspirin

[133] Schedule 5, entry for Erlotinib

insert in the column headed “Brand” after entry for the Brand “Erlotinib APOTEX”: ERLOTINIB ARX

[134] Schedule 5, entries for Estradiol

omit:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Estradiol | GRP-29372 | Transdermal patches 780 micrograms, 24 (S19A) | Transdermal | Estramon (Germany, Sandoz) Estramon 50 (Germany) |
| Estradiol | GRP-29376 | Transdermal patches 1.17 mg, 24 (S19A) | Transdermal | Estramon (Germany, Sandoz) Estramon 75 (Germany) |
| Estradiol | GRP-29483 | Transdermal patches 1.56 mg, 24 (Sandoz) (S19A) | Transdermal | Estramon (Germany, Sandoz) |
| Estradiol | GRP-29483 | Transdermal patches 1.56 mg, 24 (S19A) | Transdermal | Estramon 100 (Germany) |

[135] Schedule 5, entry for Fingolimod

insert in the column headed “Brand” after entry for the Brand “AKM Fingolimod”: Fingolimod Dr.Reddy's

[136] Schedule 5, omit entry for Follitropin beta *[GRP-27212]*

[137] Schedule 5, entries for Lacosamide in each of the forms: Tablet 100 mg; Tablet 150 mg; Tablet 200 mg; and Tablet 50 mg

omit from the column headed “Brand”: Lacoress

[138] Schedule 5, entry for Methylprednisolone *[GRP-27888]*

insert in the column headed “Brand” after entry for the Brand “Advantan (Fatty)”: Metvant (Fatty)

[139] Schedule 5, entry for Methylprednisolone *[GRP-27999]*

insert in the column headed “Brand” after entry for the Brand “Advantan”: Metvant

[140] Schedule 5, entry for Mycophenolic acid *[GRP-20011]*

omit from the column headed “Brand”: Mycophenolate APOTEX

[141] Schedule 5, entry for Olanzapine *[GRP-15884]*

omit from the column headed “Brand”: Olanzapine APOTEX

[142] Schedule 5, entry for Omeprazole in the form Tablet 20 mg

insert in the column headed “Brand” after entry for the Brand “Maxor EC Tabs”: OMEPRAZOLE-WGR

[143] Schedule 5, entry for Palonosetron

omit from the column headed “Brand”: Aloxi

[144] Schedule 5, entry for Pirfenidone

insert in the column headed “Brand” as first entry: ARX-Pirfenidone

[145] Schedule 5, entry for Quetiapine in each of the forms: Tablet 300 mg (as fumarate); and Tablet 200 mg (as fumarate)

omit from the column headed “Brand”: Quetiapine APOTEX

[146] Schedule 5, entry for Quetiapine *[GRP-19935]*

omit from the column headed “Brand”: Quetiapine APOTEX

[147] Schedule 5, entry for Rivaroxaban *[GRP-29154]*

insert in the column headed “Brand” as first entry: Rivaroxaban Lupin

[148] Schedule 5, entry for Rivaroxaban in each of the forms: Tablet 20 mg; Tablet 10 mg; and Tablet 15 mg

insert in the column headed “Brand” after entry for the Brand “Rivaroxaban Dr.Reddy’s”: Rivaroxaban Lupin

[149] Schedule 5, after entry for Roxithromycin *[GRP-20144]*

insert:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sacubitril with valsartan | GRP-29640 | Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg | Oral | Entresto Pharmacor Sacubitril/Valsartan Valtresto |
| Sacubitril with valsartan | GRP-29641 | Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg | Oral | Entresto Pharmacor Sacubitril/Valsartan Valtresto |
| Sacubitril with valsartan | GRP-29642 | Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg | Oral | Entresto Pharmacor Sacubitril/Valsartan Valtresto |

[150] Schedule 5, entries for Salbutamol

omit:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Salbutamol | GRP-21535 | Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 20 (S19A) | Inhalation | pms-SALBUTAMOL |

[151] Schedule 5, entry for Tenofovir with emtricitabine in the form Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg

omit from the column headed “Brand”: Tenofovir/Emtricitabine 300/200 APOTEX

[152] Schedule 5, after entry for Tobramycin

insert

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Tolvaptan | GRP-29585 | Pack containing 28 tablets 30 mg and 28 tablets 60 mg | Oral | Jinarc  Tolvaptan Lupin |
| Tolvaptan | GRP-29587 | Pack containing 28 tablets 30 mg and 28 tablets 90 mg | Oral | Jinarc  Tolvaptan Lupin |
| Tolvaptan | GRP-29591 | Pack containing 28 tablets 15 mg and 28 tablets 45 mg | Oral | Jinarc  Tolvaptan Lupin |