

**PB 76 of 2024**

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

*National Health Act 1953*

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

Dated 30 July 2024

**NIKOLAI TSYGANOV**

Assistant Secretary

Pricing and PBS Policy Branch

Technology Assessment and Access Division

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Schedule 1—Amendments 2

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

1 Name

1. This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (August Update) Instrument 2024*.
2. This Instrument may also be cited as PB 76 of 2024.

2 Commencement

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

| Commencement information | | |
| --- | --- | --- |
| Column 1 | Column 2 | Column 3 |
| Provisions | Commencement | Date/Details |
| 1. *The whole of this instrument* | *1 August 2024* | *1 August 2024* |

Note: This table relates only to the provisions of this instrument as originally made.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

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

3 Authority

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

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

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

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Acamprosate | Tablet (enteric coated) containing acamprosate calcium 333 mg | Oral | Acamprosate Mylan | AL | MP NP | C5366 |  | 180 | 1 |  | 180 |  |  |

1. Schedule 1, Part 1, entry for Acarbose in the form Tablet 50 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Acarbose | Tablet 50 mg | Oral | Acarbose Mylan | AF | MP NP |  |  | 90 | 5 |  | 90 |  |  |
| Acarbose | Tablet 50 mg | Oral | Acarbose Mylan | AF | MP NP |  | P14238 | 180 | 5 |  | 90 |  |  |

1. Schedule 1, Part 1, after entry for Aciclovir in the form Tablet 800 mg *[Brand: APO-Aciclovir]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Aciclovir | Tablet 800 mg | Oral | ARX-ACICLOVIR | XT | MP NP | C5959 C5967 |  | 35 | 0 |  | 35 |  |  |

1. Schedule 1, Part 1, entry for Adalimumab in the form Injection 20 mg in 0.2 mL pre-filled syringe
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adalimumab | Injection 20 mg in 0.2 mL pre-filled syringe | Injection | Humira | VE | MP | C11713 C15473 | P11713 P15473 | 2 | 0 |  | 2 |  |  |
| Adalimumab | Injection 20 mg in 0.2 mL pre-filled syringe | Injection | Humira | VE | MP | C12120 C14061 C14063 C14064 C14107 C14136 | See Note 3 | See Note 3 | See Note 3 |  | 2 |  | C(100) |
| Adalimumab | Injection 20 mg in 0.2 mL pre-filled syringe | Injection | Humira | VE | MP | C9715 C11715 C11716 C11761 C11852 C11854 C11855 | P9715 P11715 P11716 P11761 P11852 P11854 P11855 | 2 | 3 |  | 2 |  |  |
| Adalimumab | Injection 20 mg in 0.2 mL pre-filled syringe | Injection | Humira | VE | MP | C11717 C11767 C11853 C11903 C11966 C15446 C15450 | P11717 P11767 P11853 P11903 P11966 P15446 P15450 | 2 | 5 |  | 2 |  |  |
| Adalimumab | Injection 20 mg in 0.2 mL pre-filled syringe | Injection | Humira | VE | MP | C15474 C15489 | P15474 P15489 | 2 | 6 |  | 2 |  |  |

1. Schedule 1, Part 1, entry for Adalimumab in the form Injection 20 mg in 0.4 mL pre-filled syringe
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adalimumab | Injection 20 mg in 0.4 mL pre-filled syringe | Injection | Abrilada | PF | MP | C11713 | P11713 | 2 | 0 |  | 2 |  |  |
| Adalimumab | Injection 20 mg in 0.4 mL pre-filled syringe | Injection | Abrilada | PF | MP | C12120 C14061 C14063 C14064 C14107 C14136 | See Note 3 | See Note 3 | See Note 3 |  | 2 |  | C(100) |
| Adalimumab | Injection 20 mg in 0.4 mL pre-filled syringe | Injection | Abrilada | PF | MP | C9715 C11715 C11716 C11761 C11852 C11854 C11855 | P9715 P11715 P11716 P11761 P11852 P11854 P11855 | 2 | 3 |  | 2 |  |  |
| Adalimumab | Injection 20 mg in 0.4 mL pre-filled syringe | Injection | Abrilada | PF | MP | C11579 C11717 C11718 C11767 C11853 C11903 C11966 | P11579 P11717 P11718 P11767 P11853 P11903 P11966 | 2 | 5 |  | 2 |  |  |
| Adalimumab | Injection 20 mg in 0.4 mL pre-filled syringe | Injection | Amgevita | XT | MP | C11713 | P11713 | 2 | 0 |  | 1 |  |  |
| Adalimumab | Injection 20 mg in 0.4 mL pre-filled syringe | Injection | Amgevita | XT | MP | C12120 C14061 C14063 C14064 C14107 C14136 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | C(100) |
| Adalimumab | Injection 20 mg in 0.4 mL pre-filled syringe | Injection | Amgevita | XT | MP | C9715 C11715 C11716 C11761 C11852 C11854 C11855 | P9715 P11715 P11716 P11761 P11852 P11854 P11855 | 2 | 3 |  | 1 |  |  |
| Adalimumab | Injection 20 mg in 0.4 mL pre-filled syringe | Injection | Amgevita | XT | MP | C11579 C11717 C11718 C11767 C11853 C11903 C11966 | P11579 P11717 P11718 P11767 P11853 P11903 P11966 | 2 | 5 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Adalicip | LR | MP | C11713 C15473 | P11713 P15473 | 2 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Adalicip | LR | 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 pen | Injection | Adalicip | LR | 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 pen | Injection | Adalicip | LR | 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 pen | Injection | Adalicip | LR | 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 pen | Injection | Adalicip | LR | 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 pen | Injection | Adalicip | LR | MP | C15474 C15489 | P15474 P15489 | 2 | 6 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Adalicip | LR | MP | C12273 | P12273 | 4 | 2 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Adalicip | LR | MP | C11529 C12272 C12315 | P11529 P12272 P12315 | 4 | 5 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Adalicip | LR | MP | C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609 C15249 C15309 C15319 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 P15249 P15309 P15319 | 6 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Humira | VE | MP | C11713 C15473 | P11713 P15473 | 2 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Humira | VE | 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 pen | Injection | Humira | VE | 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 pen | Injection | Humira | VE | MP | C9064 C9386 C11861 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14498 C14655 C14662 C14670 | P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14498 P14655 P14662 P14670 | 2 | 3 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Humira | VE | 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 pen | Injection | Humira | VE | MP | C11704 C11711 C11717 C11767 C11853 C11865 C11867 C11903 C11906 C11966 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14656 C14713 C14730 C15446 C15450 | P11704 P11711 P11717 P11767 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14656 P14713 P14730 P15446 P15450 | 2 | 5 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Humira | VE | MP | C15474 C15489 | P15474 P15489 | 2 | 6 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Humira | VE | MP | C12273 | P12273 | 4 | 2 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Humira | VE | MP | C12272 C12315 | P12272 P12315 | 4 | 5 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Humira | VE | MP | C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609 C15249 C15309 C15319 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 P15249 P15309 P15319 | 6 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Yuflyma | EW | MP | C11713 C15473 | P11713 P15473 | 2 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Yuflyma | EW | 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 pen | Injection | Yuflyma | EW | 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 pen | Injection | Yuflyma | EW | 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 pen | Injection | Yuflyma | EW | 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 pen | Injection | Yuflyma | EW | 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 pen | Injection | Yuflyma | EW | MP | C15474 C15489 | P15474 P15489 | 2 | 6 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Yuflyma | EW | MP | C12273 | P12273 | 4 | 2 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Yuflyma | EW | MP | C11529 C12272 C12315 | P11529 P12272 P12315 | 4 | 5 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Yuflyma | EW | MP | C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609 C15249 C15309 C15319 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 P15249 P15309 P15319 | 6 | 0 |  | 2 |  |  |

1. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Adalicip; Maximum Quantity: See Note 3; Number of Repeats: See Note 3]*
   1. *insert in numerical order in the column headed “Circumstances”:* **C14107 C14136**
2. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Adalicip]*

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adalimumab | Injection 40 mg in 0.4 mL pre‑filled syringe | Injection | Adalicip | LR | MP | C14107 C14136 | P14107 P14136 | 2 | 5 |  | 2 |  | C(100) |

1. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Humira; Maximum Quantity: See Note 3; Number of Repeats: See Note 3]*
   1. *insert in numerical order in the column headed “Circumstances”:* **C14107 C14136**
2. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Humira]*

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adalimumab | Injection 40 mg in 0.4 mL pre‑filled syringe | Injection | Humira | VE | MP | C14107 C14136 | P14107 P14136 | 2 | 5 |  | 2 |  | C(100) |

1. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Yuflyma; Maximum Quantity: See Note 3; Number of Repeats: See Note 3]*
   1. *insert in numerical order in the column headed “Circumstances”:* **C14107 C14136**
2. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Yuflyma]*

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adalimumab | Injection 40 mg in 0.4 mL pre‑filled syringe | Injection | Yuflyma | EW | MP | C14107 C14136 | P14107 P14136 | 2 | 5 |  | 2 |  | C(100) |

1. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Abrilada | PF | MP | C11713 C15473 | P11713 P15473 | 2 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Abrilada | PF | MP | C12120 C14061 C14063 C14064 C14107 C14136 | See Note 3 | See Note 3 | See Note 3 |  | 2 |  | C(100) |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Abrilada | PF | 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 0.8 mL pre-filled pen | Injection | Abrilada | PF | 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 0.8 mL pre-filled pen | Injection | Abrilada | PF | MP | C11107 C12155 C12212 C13556 C13612 C14377 C14378 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Abrilada | PF | 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 0.8 mL pre-filled pen | Injection | Abrilada | PF | MP | C15474 C15489 | P15474 P15489 | 2 | 6 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Abrilada | PF | MP | C12273 | P12273 | 4 | 2 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Abrilada | PF | MP | C11529 C12272 C12315 | P11529 P12272 P12315 | 4 | 5 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Abrilada | PF | MP | C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609 C15249 C15309 C15319 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 P15249 P15309 P15319 | 6 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Amgevita | XT | MP | C11713 C15473 | P11713 P15473 | 2 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Amgevita | XT | MP | C12120 C14061 C14063 C14064 C14107 C14136 | See Note 3 | See Note 3 | See Note 3 |  | 2 |  | C(100) |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Amgevita | XT | 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 0.8 mL pre-filled pen | Injection | Amgevita | XT | 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 0.8 mL pre-filled pen | Injection | Amgevita | XT | MP | C11107 C12155 C12212 C13556 C13612 C14377 C14378 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Amgevita | XT | 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 0.8 mL pre-filled pen | Injection | Amgevita | XT | MP | C15474 C15489 | P15474 P15489 | 2 | 6 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Amgevita | XT | MP | C12273 | P12273 | 4 | 2 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Amgevita | XT | MP | C11529 C12272 C12315 | P11529 P12272 P12315 | 4 | 5 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Amgevita | XT | MP | C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609 C15249 C15309 C15319 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 P15249 P15309 P15319 | 6 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Hadlima | RF | MP | C11713 C15473 | P11713 P15473 | 2 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Hadlima | RF | MP | C12120 C14061 C14063 C14064 C14107 C14136 | See Note 3 | See Note 3 | See Note 3 |  | 2 |  | C(100) |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Hadlima | RF | 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 0.8 mL pre-filled pen | Injection | Hadlima | RF | 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 0.8 mL pre-filled pen | Injection | Hadlima | RF | MP | C11107 C12155 C12212 C13556 C13612 C14377 C14378 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Hadlima | RF | 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 0.8 mL pre-filled pen | Injection | Hadlima | RF | MP | C15474 C15489 | P15474 P15489 | 2 | 6 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Hadlima | RF | MP | C12273 | P12273 | 4 | 2 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Hadlima | RF | MP | C11529 C12272 C12315 | P11529 P12272 P12315 | 4 | 5 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Hadlima | RF | MP | C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609 C15249 C15309 C15319 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 P15249 P15309 P15319 | 6 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Hyrimoz | SZ | MP | C11713 C15473 | P11713 P15473 | 2 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | 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 0.8 mL pre-filled pen | 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 0.8 mL pre-filled pen | 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 0.8 mL pre-filled pen | 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 0.8 mL pre-filled pen | 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 0.8 mL pre-filled pen | Injection | Hyrimoz | SZ | MP | C15474 C15489 | P15474 P15489 | 2 | 6 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Hyrimoz | SZ | MP | C12273 | P12273 | 4 | 2 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Hyrimoz | SZ | MP | C11529 C12272 C12315 | P11529 P12272 P12315 | 4 | 5 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Hyrimoz | SZ | MP | C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609 C15249 C15309 C15319 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 P15249 P15309 P15319 | 6 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Idacio | PK | MP | C11713 C15473 | P11713 P15473 | 2 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Idacio | PK | MP | C12120 C14061 C14063 C14064 C14107 C14136 | See Note 3 | See Note 3 | See Note 3 |  | 2 |  | C(100) |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Idacio | PK | 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 0.8 mL pre-filled pen | Injection | Idacio | PK | 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 0.8 mL pre-filled pen | Injection | Idacio | PK | MP | C11107 C12155 C12212 C13556 C13612 C14377 C14378 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Idacio | PK | 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 0.8 mL pre-filled pen | Injection | Idacio | PK | MP | C15474 C15489 | P15474 P15489 | 2 | 6 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Idacio | PK | MP | C12273 | P12273 | 4 | 2 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Idacio | PK | MP | C11529 C12272 C12315 | P11529 P12272 P12315 | 4 | 5 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Idacio | PK | MP | C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609 C15249 C15309 C15319 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 P15249 P15309 P15319 | 6 | 0 |  | 2 |  |  |

1. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Abrilada | PF | MP | C11713 C15473 | P11713 P15473 | 2 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Abrilada | PF | MP | C12120 C14061 C14063 C14064 C14107 C14136 | See Note 3 | See Note 3 | See Note 3 |  | 2 |  | C(100) |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Abrilada | PF | 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 0.8 mL pre-filled syringe | Injection | Abrilada | PF | MP | C9386 C12174 C12194 C13599 C13681 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673 | P9386 P12174 P12194 P13599 P13681 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 | 2 | 3 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Abrilada | PF | MP | C11107 C12155 C12212 C13556 C13612 C14377 C14378 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Abrilada | PF | 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 0.8 mL pre-filled syringe | Injection | Abrilada | PF | MP | C15474 C15489 | P15474 P15489 | 2 | 6 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Abrilada | PF | 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 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Amgevita | XT | MP | C11713 C15473 | P11713 P15473 | 2 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Amgevita | XT | MP | C12120 C14061 C14063 C14064 C14107 C14136 | See Note 3 | See Note 3 | See Note 3 |  | 2 |  | C(100) |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Amgevita | XT | 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 0.8 mL pre-filled syringe | Injection | Amgevita | XT | 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 0.8 mL pre-filled syringe | Injection | Amgevita | XT | MP | C11107 C12155 C12212 C13556 C13612 C14377 C14378 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Amgevita | XT | 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 0.8 mL pre-filled syringe | Injection | Amgevita | XT | MP | C15474 C15489 | P15474 P15489 | 2 | 6 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre‑filled syringe | Injection | Amgevita | XT | 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 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Hadlima | RF | MP | C11713 C15473 | P11713 P15473 | 2 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Hadlima | RF | MP | C12120 C14061 C14063 C14064 C14107 C14136 | See Note 3 | See Note 3 | See Note 3 |  | 2 |  | C(100) |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Hadlima | RF | 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 0.8 mL pre-filled syringe | Injection | Hadlima | RF | 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 0.8 mL pre-filled syringe | Injection | Hadlima | RF | MP | C11107 C12155 C12212 C13556 C13612 C14377 C14378 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Hadlima | RF | 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 0.8 mL pre-filled syringe | Injection | Hadlima | RF | MP | C15474 C15489 | P15474 P15489 | 2 | 6 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Hadlima | RF | 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 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Hyrimoz | SZ | MP | C11713 C15473 | P11713 P15473 | 2 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 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 0.8 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 0.8 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 0.8 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 0.8 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 0.8 mL pre-filled syringe | Injection | Hyrimoz | SZ | MP | C15474 C15489 | P15474 P15489 | 2 | 6 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 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 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Idacio | PK | MP | C11713 C15473 | P11713 P15473 | 2 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Idacio | PK | MP | C12120 C14061 C14063 C14064 C14107 C14136 | See Note 3 | See Note 3 | See Note 3 |  | 2 |  | C(100) |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Idacio | PK | 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 0.8 mL pre-filled syringe | Injection | Idacio | PK | 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 0.8 mL pre-filled syringe | Injection | Idacio | PK | MP | C11107 C12155 C12212 C13556 C13612 C14377 C14378 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Idacio | PK | 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 0.8 mL pre-filled syringe | Injection | Idacio | PK | MP | C15474 C15489 | P15474 P15489 | 2 | 6 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Idacio | PK | 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 |  |  |

1. Schedule 1, Part 1, entry for Alemtuzumab in the form Solution concentrate for I.V. infusion 12 mg in 1.2 mL *[Maximum Quantity: 3; Number of Repeats: 0]*
2. *omit from the column headed “Circumstances”:* C7714
3. *omit from the column headed “Circumstances”:* C9636
4. Schedule 1, Part 1, entry for Alemtuzumab in the form Solution concentrate for I.V. infusion 12 mg in 1.2 mL *[Maximum Quantity: 5; Number of Repeats: 0]*
5. *omit from the column headed “Circumstances”:* C6847
6. *omit from the column headed “Circumstances”:* C9589
7. Schedule 1, Part 1, omit entries for Alirocumab
8. Schedule 1, Part 1, after entry for Allopurinol in the form Tablet 100 mg *[Brand: Allosig; Maximum Quantity: 400; Number of Repeats: 2]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Allopurinol | Tablet 100 mg | Oral | APO-ALLOPURINOL | TX | MP NP |  |  | 200 | 2 |  | 200 |  |  |
| Allopurinol | Tablet 100 mg | Oral | APO-ALLOPURINOL | TX | MP NP |  | P14238 | 400 | 2 |  | 200 |  |  |

1. Schedule 1, Part 1, entry for Amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexanoic acid in the form Oral liquid 125 mL, 36 (TYR Anamix junior LQ)
   1. *omit from the column headed “Listed Drug”:* **Amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexanoic acid** *substitute:* **Amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid**
2. Schedule 1, Part 1, entry for Amino acid formula with fat, carbohydrate, vitamins, minerals, and trace elements, without methionine and supplemented with docosahexanoic acid in the form Oral liquid 125 mL, 36 (HCU Anamix junior LQ)
   1. *omit from the column headed “Listed Drug”:* **Amino acid formula with fat, carbohydrate, vitamins, minerals, and trace elements, without methionine and supplemented with docosahexanoic acid** *substitute:* **Amino acid formula with fat, carbohydrate, vitamins, minerals, and trace elements, without methionine and supplemented with docosahexaenoic acid**
3. Schedule 1, Part 1, after entry for Amino acid formula with vitamins and minerals without phenylalanine in the form Oral liquid 125 mL, 30 (PKU Lophlex LQ 20)
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Amino acid formula with vitamins and minerals without phenylalanine | Oral liquid 125 mL, 30 (PKU Lophlex Select LQ) | Oral | PKU Lophlex Select LQ | NU | MP NP | C4295 |  | 4 | 5 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexanoic acid
   1. *omit from the column headed “Listed Drug”:* **Amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexanoic acid** *substitute:* **Amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexaenoic acid**
2. Schedule 1, Part 1, entry for Amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine in the form Oral powder 400 g (PKU Start)
   1. *omit from the column headed “Pack Quantity”:* **1** *substitute:* **4**
3. Schedule 1, Part 1, entry for Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides | Oral powder 400 g (Alfamino) | Oral | Alfamino | NT | MP NP | C4305 C4312 C4323 C4330 C4337 C4338 C4339 C4345 C4352 C4415 C5945 C5974 |  | 8 | 5 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Amoxicillin in the form Powder for paediatric oral drops 100 mg (as trihydrate) per mL, 20 mL
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Amoxicillin | Powder for paediatric oral drops 100 mg (as trihydrate) per mL, 20 mL | Oral | Amoxil | AS | PDP |  |  | 1 | 0 |  | 1 |  |  |
| Amoxicillin | Powder for paediatric oral drops 100 mg (as trihydrate) per mL, 20 mL | Oral | Amoxil | AS | MP NP |  |  | 1 | 1 |  | 1 |  |  |
| Amoxicillin | Powder for paediatric oral drops 100 mg (as trihydrate) per mL, 20 mL | Oral | Amoxil | AS | MP NP |  | P5863 | 1 CN5863 | 1 CN5863 |  | 1 |  |  |

1. Schedule 1, Part 1, after entry for Amoxicillin with clavulanic acid in the form Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *[Brand: AlphaClav Duo; Maximum Quantity: 20; Number of Repeats: 0]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Amoxicillin with clavulanic acid | Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) | Oral | Alphaclav Duo Viatris | AL | MP NP MW | C5832 C5893 | P5832 P5893 | 10 | 0 |  | 10 |  |  |
| Amoxicillin with clavulanic acid | Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) | Oral | Alphaclav Duo Viatris | AL | PDP | C5833 C5894 | P5833 P5894 | 10 | 0 |  | 10 |  |  |
| Amoxicillin with clavulanic acid | Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) | Oral | Alphaclav Duo Viatris | AL | MP NP | C10405 | P10405 | 20 | 0 |  | 10 |  |  |

1. Schedule 1, Part 1, entry for Arsenic

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Arsenic | Injection concentrate containing arsenic trioxide 10 mg in 10 mL | Injection | Arsenic Trioxide Accord | OC | MP | C4793 C5997 C6018 |  | See Note 3 | See Note 3 |  | 10 |  | D(100) |
| Arsenic | Injection concentrate containing arsenic trioxide 10 mg in 10 mL | Injection | Arsenic Trioxide Juno | JU | MP | C4793 C5997 C6018 |  | See Note 3 | See Note 3 |  | 10 |  | D(100) |
| Arsenic | Injection concentrate containing arsenic trioxide 10 mg in 10 mL | Injection | Arsenic Trioxide‑AFT | AE | MP | C4793 C5997 C6018 |  | See Note 3 | See Note 3 |  | 10 |  | D(100) |
| Arsenic | Injection concentrate containing arsenic trioxide 10 mg in 10 mL | Injection | Phenasen | FF | MP | C4793 C5997 C6018 |  | See Note 3 | See Note 3 |  | 10 |  | D(100) |

1. Schedule 1, Part 1, entry for Atezolizumab

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Atezolizumab | Solution concentrate for I.V. infusion 840 mg in 14 mL | Injection | Tecentriq | RO | MP | C10215 C10257 C10509 C10972 C13446 C13451 |  | See Note 3 | See Note 3 |  | 1 |  | PB(100) |
| Atezolizumab | Solution concentrate for I.V. infusion 1200 mg in 20 mL | Injection | Tecentriq | RO | MP | C10125 C10206 C10216 C10297 C10521 C10917 C10939 C13442 C13443 C13448 |  | See Note 3 | See Note 3 |  | 1 |  | PB(100) |
| Atezolizumab | Solution for subcutaneous injection 1875 mg in 15 mL | Injection | Tecentriq SC | RO | MP | C10206 C10939 | P10206 P10939 | 1 | 3 |  | 1 |  |  |
| Atezolizumab | Solution for subcutaneous injection 1875 mg in 15 mL | Injection | Tecentriq SC | RO | MP | C10521 | P10521 | 1 | 4 |  | 1 |  |  |
| Atezolizumab | Solution for subcutaneous injection 1875 mg in 15 mL | Injection | Tecentriq SC | RO | MP | C10125 C13443 C13448 | P10125 P13443 P13448 | 1 | 5 |  | 1 |  |  |
| Atezolizumab | Solution for subcutaneous injection 1875 mg in 15 mL | Injection | Tecentriq SC | RO | MP | C10216 C10297 C15455 | P10216 P10297 P15455 | 1 | 7 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Avelumab

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Avelumab | Solution concentrate for I.V. infusion 200 mg in 10 mL | Injection | Bavencio | SG | MP | C8947 C10023 C13290 C15485 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

1. Schedule 1, Part 1, entry for Axitinib in the form Tablet 1 mg *[Maximum Quantity: 56; Number of Repeats: 2]*

*omit from the column headed “Variations”:* V7433

1. Schedule 1, Part 1, entry for Axitinib in the form Tablet 1 mg *[Maximum Quantity: 56; Number of Repeats: 5]*

*omit from the column headed “Variations”:* V8588

1. Schedule 1, Part 1, entry for Axitinib in the form Tablet 5 mg *[Maximum Quantity: 56; Number of Repeats: 2]*

*omit from the column headed “Variations”:* V7433

1. Schedule 1, Part 1, entry for Axitinib in the form Tablet 5 mg *[Maximum Quantity: 56; Number of Repeats: 5]*

*omit from the column headed “Variations”:* V8588

1. Schedule 1, Part 1, entry for Azithromycin in the form Tablet 500 mg (as dihydrate) *[Brand: APO‑Azithromycin; Maximum Quantity: 2; Number of Repeats: 0]*

*insert in numerical order in the column headed “Purposes”:* **P5718 P5772**

1. Schedule 1, Part 1, entry for Azithromycin in the form Tablet 500 mg (as dihydrate) *[Brand: APO‑Azithromycin; Maximum Quantity: 2; Number of Repeats: 2]*

*insert in the column headed “Purposes”:* **P5637**

1. Schedule 1, Part 1, entry for Azithromycin in the form Tablet 500 mg (as dihydrate) *[Brand: Azithromycin Mylan; Maximum Quantity: 2; Number of Repeats: 0]*

*insert in numerical order in the column headed “Purposes”:* **P5718 P5772**

1. Schedule 1, Part 1, entry for Azithromycin in the form Tablet 500 mg (as dihydrate) *[Brand: Azithromycin Mylan; Maximum Quantity: 2; Number of Repeats: 2]*

*insert in the column headed “Purposes”:* **P5637**

1. Schedule 1, Part 1, entry for Azithromycin in the form Tablet 500 mg (as dihydrate) *[Brand: Azithromycin Sandoz; Maximum Quantity: 2; Number of Repeats: 0]*

*insert in numerical order in the column headed “Purposes”:* **P5718 P5772**

1. Schedule 1, Part 1, entry for Azithromycin in the form Tablet 500 mg (as dihydrate) *[Brand: Azithromycin Sandoz; Maximum Quantity: 2; Number of Repeats: 2]*

*insert in the column headed “Purposes”:* **P5637**

1. Schedule 1, Part 1, entry for Azithromycin in the form Tablet 500 mg (as dihydrate) *[Brand: Azithromycin Viatris; Maximum Quantity: 2; Number of Repeats: 0]*

*insert in numerical order in the column headed “Purposes”:* **P5718 P5772**

1. Schedule 1, Part 1, entry for Azithromycin in the form Tablet 500 mg (as dihydrate) *[Brand: Azithromycin Viatris; Maximum Quantity: 2; Number of Repeats: 2]*

*insert in the column headed “Purposes”:* **P5637**

1. Schedule 1, Part 1, entry for Azithromycin in the form Tablet 500 mg (as dihydrate) *[Brand: ZITHRO; Maximum Quantity: 2; Number of Repeats: 0]*

*insert in numerical order in the column headed “Purposes”:* **P5718 P5772**

1. Schedule 1, Part 1, entry for Azithromycin in the form Tablet 500 mg (as dihydrate) *[Brand: ZITHRO; Maximum Quantity: 2; Number of Repeats: 2]*

*insert in the column headed “Purposes”:* **P5637**

1. Schedule 1, Part 1, entry for Azithromycin in the form Tablet 500 mg (as dihydrate) *[Brand: Zithromax; Maximum Quantity: 2; Number of Repeats: 0]*

*insert in numerical order in the column headed “Purposes”:* **P5718 P5772**

1. Schedule 1, Part 1, entry for Azithromycin in the form Tablet 500 mg (as dihydrate) *[Brand: Zithromax; Maximum Quantity: 2; Number of Repeats: 2]*

*insert in the column headed “Purposes”:* **P5637**

1. Schedule 1, Part 1, entry for Azithromycin in the form Tablet 600 mg (as dihydrate)
2. *omit from the column headed “Maximum Quantity”:* See Note 3 *substitute:* 16
3. *omit from the column headed “Number of Repeats”:* See Note 3 *substitute:* 5
4. Schedule 1, Part 1, entry for Baclofen in the form Intrathecal injection 10 mg in 5 mL *[Brand: Bacthecal]*
5. *omit from the column headed “Maximum Quantity”:* See Note 3 *substitute:* 10
6. *omit from the column headed “Number of Repeats”:* See Note 3 *substitute:* 0
7. Schedule 1, Part 1, entry for Baclofen in the form Intrathecal injection 10 mg in 5 mL *[Brand: Lioresal Intrathecal]*
8. *omit from the column headed “Maximum Quantity”:* See Note 3 *substitute:* 10
9. *omit from the column headed “Number of Repeats”:* See Note 3 *substitute:* 0
10. Schedule 1, Part 1, entry for Baclofen in the form Intrathecal injection 10 mg in 5 mL *[Brand: Sintetica Baclofen Intrathecal]*
11. *omit from the column headed “Maximum Quantity”:* See Note 3 *substitute:* 10
12. *omit from the column headed “Number of Repeats”:* See Note 3 *substitute:* 0
13. Schedule 1, Part 1, entry for Baclofen in the form Intrathecal injection 40 mg in 20 mL
14. *omit from the column headed “Maximum Quantity”:* See Note 3 *substitute:* 2
15. *omit from the column headed “Number of Repeats”:* See Note 3 *substitute:* 0
16. Schedule 1, Part 1, entry for Beclometasone with formoterol in the form Pressurised inhalation containing beclometasone dipropionate 100 micrograms and formoterol fumarate dihydrate 6 micrograms per dose,120 dose

*omit from the column headed “Circumstances”:* **C11057** *substitute:* **C15469**

1. Schedule 1, Part 1, entry for Benralizumab

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Benralizumab | Injection 30 mg in 1 mL single dose pre‑filled pen | Injection | Fasenra Pen | AP | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |

1. Schedule 1, Part 1, entry for Benzatropine in the form Injection containing benzatropine mesilate 2 mg in 2 mL

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Benzatropine | Injection containing benzatropine mesilate 2 mg in 2 mL | Injection | Benzatropine Injection | FF | MP NP PDP |  |  | 5 | 0 |  | 5 |  |  |

1. Schedule 1, Part 1, entry for Benzylpenicillin in the form Powder for injection 3 g (as sodium)

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Benzylpenicillin | Powder for injection 3 g (as sodium) | Injection | BenPen | CS | MP NP PDP |  |  | 10 | 0 |  | 1 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Betaxolol | Eye drops, solution, 5 mg (as hydrochloride) per mL, 5 mL | Application to the eye | Betoptic | NV | MP AO |  |  | 1 | 5 |  | 1 |  |  |
| Betaxolol | Eye drops, solution, 5 mg (as hydrochloride) per mL, 5 mL | Application to the eye | BetoQuin | NM | MP AO |  |  | 1 | 5 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Bimatoprost

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bimatoprost | Eye drops 300 micrograms per mL, 3 mL | Application to the eye | Bimatoprost Sandoz | SZ | MP AO |  |  | 1 | 5 |  | 1 |  |  |
| Bimatoprost | Eye drops 300 micrograms per mL, 3 mL | Application to the eye | Bimprozt | TY | MP AO |  |  | 1 | 5 |  | 1 |  |  |
| Bimatoprost | Eye drops 300 micrograms per mL, 3 mL | Application to the eye | Bimtop | AF | MP AO |  |  | 1 | 5 |  | 1 |  |  |
| Bimatoprost | Eye drops 300 micrograms per mL, 3 mL | Application to the eye | Lumigan | VE | MP AO |  |  | 1 | 5 |  | 1 |  |  |
| Bimatoprost | Eye drops 300 micrograms per mL, single dose units 0.4 mL, 30 | Application to the eye | Lumigan PF | VE | MP AO |  |  | 1 | 5 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Bosentan in the form Tablet 125 mg (as monohydrate)
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bosentan | Tablet 125 mg (as monohydrate) | Oral | Bosentan Cipla | LR | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 60 |  | D(100) |

1. Schedule 1, Part 1, entry for Brentuximab vedotin

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Brentuximab vedotin | Powder for I.V. infusion 50 mg | Injection | Adcetris | TK | MP | C13134 C13179 C13181 C13182 C13208 C13209 C13212 C13231 C13259 C13261 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Brimonidine | Eye drops containing brimonidine tartrate 1.5 mg per mL, 5 mL | Application to the eye | Alphagan P 1.5 | VE | MP AO |  |  | 1 | 5 |  | 1 |  |  |
| Brimonidine | Eye drops containing brimonidine tartrate 2 mg per mL, 5 mL | Application to the eye | Alphagan | VE | MP AO |  |  | 1 | 5 |  | 1 |  |  |
| Brimonidine | Eye drops containing brimonidine tartrate 2 mg per mL, 5 mL | Application to the eye | Enidin | VB | MP AO |  |  | 1 | 5 |  | 1 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Brinzolamide | Eye drops 10 mg per mL, 5 mL | Application to the eye | Azopt | NV | MP AO |  |  | 1 | 5 |  | 1 |  |  |
| Brinzolamide | Eye drops 10 mg per mL, 5 mL | Application to the eye | BrinzoQuin | NM | MP AO |  |  | 1 | 5 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Cabozantinib in the form Tablet 20 mg *[Maximum Quantity: 30; Number of Repeats: 2]*
2. *insert in numerical order in the column headed “Circumstances”:* **C15454**
3. *insert in numerical order in the column headed “Purposes”:* **P15454**
4. Schedule 1, Part 1, entry for Cabozantinib in the form Tablet 20 mg *[Maximum Quantity: 30; Number of Repeats: 5]*
5. *insert in numerical order in the column headed “Circumstances”:* **C15479 C15518**
6. *insert in numerical order in the column headed “Purposes”:* **P15479 P15518**
7. Schedule 1, Part 1, entry for Cabozantinib in the form Tablet 40 mg *[Maximum Quantity: 30; Number of Repeats: 2]*
8. *insert in numerical order in the column headed “Circumstances”:* **C15454**
9. *insert in numerical order in the column headed “Purposes”:* **P15454**
10. Schedule 1, Part 1, entry for Cabozantinib in the form Tablet 40 mg *[Maximum Quantity: 30; Number of Repeats: 5]*
11. *insert in numerical order in the column headed “Circumstances”:* **C15479 C15518**
12. *insert in numerical order in the column headed “Purposes”:* **P15479 P15518**
13. Schedule 1, Part 1, entry for Cabozantinib in the form Tablet 60 mg *[Maximum Quantity: 30; Number of Repeats: 2]*
14. *insert in numerical order in the column headed “Circumstances”:* **C15454**
15. *insert in numerical order in the column headed “Purposes”:* **P15454**
16. Schedule 1, Part 1, entry for Cabozantinib in the form Tablet 60 mg *[Maximum Quantity: 30; Number of Repeats: 5]*
17. *insert in numerical order in the column headed “Circumstances”:* **C15479 C15518**
18. *insert in numerical order in the column headed “Purposes”:* **P15479 P15518**
19. Schedule 1, Part 1, entry for Calcium in the form Tablet, chewable, 500 mg (as carbonate) *[Authorised Prescriber: MP; Maximum Quantity: 240; Number of Repeats: 1]*
    1. *omit from the column headed “Authorised Prescriber”:* **MP** *substitute:* **MP NP**
20. Schedule 1, Part 1, entry for Calcium in the form Tablet, chewable, 500 mg (as carbonate)
    1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Calcium | Tablet, chewable, 500 mg (as carbonate) | Oral | Cal-500 | PP | NP | C4586 |  | 240 | 1 |  | 120 |  |  |

1. Schedule 1, Part 1, entry for Calcium in the form Tablet, chewable, 500 mg (as carbonate) *[Maximum Quantity: 480; Number of  
   Repeats: 1]*
   1. *omit from the column headed “Authorised Prescriber”:* **MP** *substitute:* **MP NP**
2. Schedule 1, Part 1, entry for Cefalexin in the form Capsule 250 mg (as monohydrate) *[Brand: APO‑Cephalexin; Maximum Quantity: 20; Number of Repeats: 0]*
   1. *omit from the column headed “Authorised Prescriber”:* **MP NP MW** *substitute:* **MP NP MW PDP**
   2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cefalexin | Capsule 250 mg (as monohydrate) | Oral | APO‑Cephalexin | TX | PDP |  |  | 20 | 0 |  | 20 |  |  |

1. Schedule 1, Part 1, entry for Cefalexin in the form Capsule 250 mg (as monohydrate) *[Brand: Ibilex 250; Maximum Quantity: 20; Number of Repeats: 0]*
2. *omit from the column headed “Authorised Prescriber”:* **MP NP MW** *substitute:* **MP NP MW PDP**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cefalexin | Capsule 250 mg (as monohydrate) | Oral | Ibilex 250 | AF | PDP |  |  | 20 | 0 |  | 20 |  |  |

1. Schedule 1, Part 1, entry for Cefalexin in the form Capsule 250 mg (as monohydrate) *[Brand:* *Keflex; Maximum Quantity: 20; Number of Repeats: 0]*
2. *omit from the column headed “Authorised Prescriber”:* **MP NP MW** *substitute:* **MP NP MW PDP**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cefalexin | Capsule 250 mg (as monohydrate) | Oral | Keflex | AS | PDP |  |  | 20 | 0 |  | 20 |  |  |

1. Schedule 1, Part 1, entry for Cefalexin in the form Capsule 500 mg (as monohydrate) *[Brand: APO‑Cephalexin; Maximum Quantity: 20; Number of Repeats: 0]*
2. *omit from the column headed “Authorised Prescriber”:* **MP NP MW** *substitute:* **MP NP MW PDP**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cefalexin | Capsule 500 mg (as monohydrate) | Oral | APO‑Cephalexin | TX | PDP |  |  | 20 | 0 |  | 20 |  |  |

1. Schedule 1, Part 1, entry for Cefalexin in the form Capsule 500 mg (as monohydrate) *[Brand: Blooms The Chemist Cefalexin; Maximum Quantity: 20; Number of Repeats: 0]*
2. *omit from the column headed “Authorised Prescriber”:* **MP NP MW** *substitute:* **MP NP MW PDP**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cefalexin | Capsule 500 mg (as monohydrate) | Oral | Blooms The Chemist Cefalexin | BG | PDP |  |  | 20 | 0 |  | 20 |  |  |

1. Schedule 1, Part 1, entry for Cefalexin in the form Capsule 500 mg (as monohydrate) *[Brand: Cefalexin Sandoz; Maximum Quantity: 20; Number of Repeats: 0]*
2. *omit from the column headed “Authorised Prescriber”:* **MP NP MW** *substitute:* **MP NP MW PDP**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cefalexin | Capsule 500 mg (as monohydrate) | Oral | Cefalexin Sandoz | SZ | PDP |  |  | 20 | 0 |  | 20 |  |  |

1. Schedule 1, Part 1, entry for Cefalexin in the form Capsule 500 mg (as monohydrate) *[Brand: Cephalex 500; Maximum Quantity: 20; Number of Repeats: 0]*
2. *omit from the column headed “Authorised Prescriber”:* **MP NP MW** *substitute:* **MP NP MW PDP**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cefalexin | Capsule 500 mg (as monohydrate) | Oral | Cephalex 500 | CR | PDP |  |  | 20 | 0 |  | 20 |  |  |

1. Schedule 1, Part 1, entry for Cefalexin in the form Capsule 500 mg (as monohydrate) *[Brand: Cephalexin generichealth; Maximum Quantity: 20; Number of Repeats: 0]*
2. *omit from the column headed “Authorised Prescriber”:* **MP NP MW** *substitute:* **MP NP MW PDP**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cefalexin | Capsule 500 mg (as monohydrate) | Oral | Cephalexin generichealth | GQ | PDP |  |  | 20 | 0 |  | 20 |  |  |

1. Schedule 1, Part 1, entry for Cefalexin in the form Capsule 500 mg (as monohydrate) *[Brand: Ibilex 500; Maximum Quantity: 20; Number of Repeats: 0]*
2. *omit from the column headed “Authorised Prescriber”:* **MP NP MW** *substitute:* **MP NP MW PDP**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cefalexin | Capsule 500 mg (as monohydrate) | Oral | Ibilex 500 | AF | PDP |  |  | 20 | 0 |  | 20 |  |  |

1. Schedule 1, Part 1, entry for Cefalexin in the form Capsule 500 mg (as monohydrate) *[Brand: Keflex; Maximum Quantity: 20; Number of Repeats: 0]*
2. *omit from the column headed “Authorised Prescriber”:* **MP NP MW** *substitute:* **MP NP MW PDP**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cefalexin | Capsule 500 mg (as monohydrate) | Oral | Keflex | AS | PDP |  |  | 20 | 0 |  | 20 |  |  |

1. Schedule 1, Part 1, entry for Cefalexin in the form Capsule 500 mg (as monohydrate) *[Brand: NOUMED CEFALEXIN; Maximum Quantity: 20; Number of Repeats: 0]*
2. *omit from the column headed “Authorised Prescriber”:* **MP NP MW** *substitute:* **MP NP MW PDP**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cefalexin | Capsule 500 mg (as monohydrate) | Oral | NOUMED CEFALEXIN | VO | PDP |  |  | 20 | 0 |  | 20 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cefazolin | Powder for injection 500 mg (as sodium) | Injection | Cefazolin-AFT | AE | MP NP | C5826 C5867 C5881 C5890 |  | 10 | 0 |  | 5 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cefazolin | Powder for injection 2 g (as sodium) | Injection | Cephazolin Alphapharm | AF | MP NP | C5826 C5867 C5881 C5890 |  | 10 | 0 |  | 10 |  |  |

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

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

1. Schedule 1, Part 1, entry for Cetuximab in the form Solution for I.V. infusion 100 mg in 20 mL
2. *omit from the column headed “Circumstances”:* C4788 *substitute:* C4785 C4788 C4794 C4908 C4912 C12016 C12045 C12470 C12483
3. *omit from the column headed “Purposes”:* P4788
4. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cetuximab | Solution for I.V. infusion 100 mg in 20 mL | Injection | Erbitux | SG | MP | C4785 C4794 | P4785 P4794 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Cetuximab | Solution for I.V. infusion 100 mg in 20 mL | Injection | Erbitux | SG | MP | C4908 C12045 C12483 | P4908 P12045 P12483 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Cetuximab | Solution for I.V. infusion 100 mg in 20 mL | Injection | Erbitux | SG | MP | C12016 C12470 | P12016 P12470 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Cetuximab | Solution for I.V. infusion 100 mg in 20 mL | Injection | Erbitux | SG | MP | C4912 | P4912 | See Note 3 | See Note 3 |  | 1 |  | D(100) |

1. Schedule 1, Part 1, entry for Cetuximab in the form Solution for I.V. infusion 500 mg in 100 mL
2. *omit from the column headed “Circumstances”:* C4788 *substitute:* C4785 C4788 C4794 C4908 C4912 C12016 C12045 C12470 C12483
3. *omit from the column headed “Purposes”:* P4788
4. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cetuximab | Solution for I.V. infusion 500 mg in 100 mL | Injection | Erbitux | SG | MP | C4785 C4794 | P4785 P4794 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Cetuximab | Solution for I.V. infusion 500 mg in 100 mL | Injection | Erbitux | SG | MP | C4908 C12045 C12483 | P4908 P12045 P12483 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Cetuximab | Solution for I.V. infusion 500 mg in 100 mL | Injection | Erbitux | SG | MP | C12016 C12470 | P12016 P12470 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Cetuximab | Solution for I.V. infusion 500 mg in 100 mL | Injection | Erbitux | SG | MP | C4912 | P4912 | See Note 3 | See Note 3 |  | 1 |  | D(100) |

1. Schedule 1, Part 1, entry for Cinacalcet in the form Tablet 90 mg (as hydrochloride)
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cinacalcet | Tablet 90 mg (as hydrochloride) | Oral | Cinacalcet Mylan | AF | MP NP | C10068 |  | 28 | 5 |  | 28 |  |  |
| Cinacalcet | Tablet 90 mg (as hydrochloride) | Oral | Cinacalcet Mylan | AF | MP | C10063 C10067 C10073 |  | 56 | 5 |  | 28 |  | C(100) |

1. Schedule 1, Part 1, entry for Clozapine in the form Oral liquid 50 mg per mL, 100 mL *[Brand: Clopine Suspension]*
2. *omit from the column headed “Circumstances”:* C10063 C10067 C10073 *substitute:* C4998 C5015 C9490
3. *omit from the column headed “Maximum Quantity”:* 56 *substitute:* 1
4. *omit from the column headed “Number of Repeats”:* 5 *substitute:* 0
5. Schedule 1, Part 1, entry for Clozapine in the form Oral liquid 50 mg per mL, 100 mL *[Brand: Versacloz]*
6. *omit from the column headed “Circumstances”:* C10063 C10067 C10073 *substitute:* C4998 C5015 C9490
7. *omit from the column headed “Maximum Quantity”:* 56 *substitute:* 1
8. *omit from the column headed “Number of Repeats”:* 5 *substitute:* 0
9. Schedule 1, Part 1, entry for Codeine in the form Tablet containing codeine phosphate hemihydrate 30 mg *[Maximum Quantity: 10; Number of Repeats: 0]*
10. *omit from the column headed “Authorised Prescriber”:* PDP *substitute:* MP NP PDP
11. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Codeine | Tablet containing codeine phosphate hemihydrate 30 mg | Oral | Aspen Pharma Pty Ltd | AS | MP NP | C10766 | P10766 | 10 | 0 |  | 20 |  |  |

1. Schedule 1, Part 1, entry for Codeine with paracetamol
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | APO‑ Paracetamol/Codeine 500/30 | TX | MP NP PDP | C10766 | P10766 | 10 | 0 |  | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | APO‑ Paracetamol/Codeine 500/30 | TX | MP NP | C10764 C10771 C10772 | P10764 P10771 P10772 | 20 | 0 | V10764 V10771 V10772 | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | APO‑ Paracetamol/Codeine 500/30 | TX | PDP | C10768 | P10768 | 20 | 0 |  | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | APX‑Paracetamol/Codeine | TY | MP NP PDP | C10766 | P10766 | 10 | 0 |  | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | APX‑Paracetamol/Codeine | TY | MP NP | C10764 C10771 C10772 | P10764 P10771 P10772 | 20 | 0 | V10764 V10771 V10772 | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | APX‑Paracetamol/Codeine | TY | PDP | C10768 | P10768 | 20 | 0 |  | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | Codalgin Forte | AF | MP NP PDP | C10766 | P10766 | 10 | 0 |  | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | Codalgin Forte | AF | MP NP | C10764 C10771 C10772 | P10764 P10771 P10772 | 20 | 0 | V10764 V10771 V10772 | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | Codalgin Forte | AF | PDP | C10768 | P10768 | 20 | 0 |  | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | Codapane Forte 500/30 | AL | MP NP PDP | C10766 | P10766 | 10 | 0 |  | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | Codapane Forte 500/30 | AL | MP NP | C10764 C10771 C10772 | P10764 P10771 P10772 | 20 | 0 | V10764 V10771 V10772 | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | Codapane Forte 500/30 | AL | PDP | C10768 | P10768 | 20 | 0 |  | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | Comfarol Forte | SZ | MP NP PDP | C10766 | P10766 | 10 | 0 |  | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | Comfarol Forte | SZ | MP NP | C10764 C10771 C10772 | P10764 P10771 P10772 | 20 | 0 | V10764 V10771 V10772 | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | Comfarol Forte | SZ | PDP | C10768 | P10768 | 20 | 0 |  | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | Panadeine Forte | SW | MP NP PDP | C10766 | P10766 | 10 | 0 |  | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | Panadeine Forte | SW | MP NP | C10764 C10771 C10772 | P10764 P10771 P10772 | 20 | 0 | V10764 V10771 V10772 | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | Panadeine Forte | SW | PDP | C10768 | P10768 | 20 | 0 |  | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | Paracetamol/Codeine GH 500/30 | GQ | MP NP PDP | C10766 | P10766 | 10 | 0 |  | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | Paracetamol/Codeine GH 500/30 | GQ | MP NP | C10764 C10771 C10772 | P10764 P10771 P10772 | 20 | 0 | V10764 V10771 V10772 | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | Paracetamol/Codeine GH 500/30 | GQ | PDP | C10768 | P10768 | 20 | 0 |  | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | Prodeine Forte | AV | MP NP PDP | C10766 | P10766 | 10 | 0 |  | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | Prodeine Forte | AV | MP NP | C10764 C10771 C10772 | P10764 P10771 P10772 | 20 | 0 | V10764 V10771 V10772 | 20 |  |  |
| Codeine with paracetamol | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | Oral | Prodeine Forte | AV | PDP | C10768 | P10768 | 20 | 0 |  | 20 |  |  |

1. Schedule 1, Part 1, entry for Dabigatran etexilate in the form Capsule 75 mg (as mesilate)
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dabigatran etexilate | Capsule 75 mg (as mesilate) | Oral | PHARMACOR DABIGATRAN | CR | MP NP | C4402 | P4402 | 60 | 0 |  | 60 |  |  |

1. Schedule 1, Part 1, after entry for Dasatinib in the form Tablet 20 mg *[Brand: DASATINIB-TEVA; Maximum Quantity: 60; Number of Repeats: 5]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dasatinib | Tablet 20 mg | Oral | Dasatinib Viatris | AL | MP | C9367 C9468 C9469 C9549 | P9367 P9468 P9469 P9549 | 60 | 2 |  | 60 |  |  |
| Dasatinib | Tablet 20 mg | Oral | Dasatinib Viatris | AL | MP | C12522 C12524 C12530 C12561 C12565 C12570 | P12522 P12524 P12530 P12561 P12565 P12570 | 60 | 5 |  | 60 |  |  |

1. Schedule 1, Part 1, after entry for Dasatinib in the form Tablet 50 mg *[Brand: DASATINIB-TEVA; Maximum Quantity: 60; Number of Repeats: 5]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dasatinib | Tablet 50 mg | Oral | Dasatinib Viatris | AL | MP | C9367 C9468 C9469 C9549 | P9367 P9468 P9469 P9549 | 60 | 2 |  | 60 |  |  |
| Dasatinib | Tablet 50 mg | Oral | Dasatinib Viatris | AL | MP | C12522 C12524 C12530 C12561 C12565 C12570 | P12522 P12524 P12530 P12561 P12565 P12570 | 60 | 5 |  | 60 |  |  |

1. Schedule 1, Part 1, after entry for Dasatinib in the form Tablet 70 mg *[Brand: DASATINIB-TEVA; Maximum Quantity: 60; Number of Repeats: 5]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dasatinib | Tablet 70 mg | Oral | Dasatinib Viatris | AL | MP | C9367 C9468 C9469 C9549 | P9367 P9468 P9469 P9549 | 60 | 2 |  | 60 |  |  |
| Dasatinib | Tablet 70 mg | Oral | Dasatinib Viatris | AL | MP | C12522 C12524 C12530 C12561 C12565 C12570 | P12522 P12524 P12530 P12561 P12565 P12570 | 60 | 5 |  | 60 |  |  |

1. Schedule 1, Part 1, after entry for Dasatinib in the form Tablet 100 mg *[Brand: DASATINIB-TEVA; Maximum Quantity: 30; Number of Repeats: 5]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dasatinib | Tablet 100 mg | Oral | Dasatinib Viatris | AL | MP | C9367 C9468 C9469 C9549 | P9367 P9468 P9469 P9549 | 30 | 2 |  | 30 |  |  |
| Dasatinib | Tablet 100 mg | Oral | Dasatinib Viatris | AL | MP | C12522 C12524 C12530 C12561 C12565 C12570 | P12522 P12524 P12530 P12561 P12565 P12570 | 30 | 5 |  | 30 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Durvalumab | Solution concentrate for I.V. infusion 120 mg in 2.4 mL | Injection | Imfinzi | AP | MP | C10206 C10509 C12271 C14708 C15500 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Durvalumab | Solution concentrate for I.V. infusion 500 mg in 10 mL | Injection | Imfinzi | AP | MP | C10206 C10509 C12271 C14708 C15500 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

1. Schedule 1, Part 1, entry for Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor
   1. *insert as first entry:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor | Pack containing 28 sachets containing granules elexacaftor 80 mg with tezacaftor 40 mg and with ivacaftor 60 mg and 28 sachets containing granules ivacaftor 59.5 mg | Oral | Trikafta | VR | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor | Pack containing 28 sachets containing granules elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 sachets containing granules ivacaftor 75 mg | Oral | Trikafta | VR | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ezetimibe | Tablet 10 mg | Oral | Blooms The Chemist Ezetimibe | IB | MP NP | C7966 C7990 C7996 | P7966 P7990 P7996 | 30 | 5 |  | 30 |  |  |
| Ezetimibe | Tablet 10 mg | Oral | Blooms The Chemist Ezetimibe | IB | MP NP | C14249 C14283 C14310 | P14249 P14283 P14310 | 60 | 5 |  | 30 |  |  |

1. Schedule 1, Part 1, entry for Felodipine in the form Tablet 2.5 mg (extended release) *[Brand: Felodur ER 2.5 mg]*
   1. *omit from the column headed “Responsible Person” (all instances):* **TX** *substitute (all instances):* **IY**
2. Schedule 1, Part 1, entry for Felodipine in the form Tablet 2.5 mg (extended release) *[Brand: Plendil ER]*
   1. *omit from the column headed “Responsible Person” (all instances):* **GX** *substitute (all instances):* **IX**
3. Schedule 1, Part 1, entry for Felodipine in the form Tablet 5 mg (extended release) *[Brand: Felodur ER 5 mg]*
   1. *omit from the column headed “Responsible Person” (all instances):* **TX** *substitute (all instances):* **IY**
4. Schedule 1, Part 1, entry for Felodipine in the form Tablet 5 mg (extended release) *[Brand: Plendil ER]*
   1. *omit from the column headed “Responsible Person” (all instances):* **GX** *substitute (all instances):* **IX**
5. Schedule 1, Part 1, entry for Felodipine in the form Tablet 10 mg (extended release) *[Brand: Felodur ER 10 mg]*
   1. *omit from the column headed “Responsible Person” (all instances):* **TX** *substitute (all instances):* **IY**
6. Schedule 1, Part 1, entry for Felodipine in the form Tablet 10 mg (extended release) *[Brand: Plendil ER]*
   1. *omit from the column headed “Responsible Person” (all instances):* **GX** *substitute (all instances):* **IX**
7. Schedule 1, Part 1, omit entries for Fluorometholone
8. Schedule 1, Part 1, entry for Folinic acid
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Folinic acid | Injection containing calcium folinate equivalent to 100 mg folinic acid in 10 mL | Injection | Leucovorin Calcium (Pfizer Australia Pty Ltd) | PF | MP |  |  | 10 | 1 |  | 10 |  |  |

1. Schedule 1, Part 1, entry for Gilteritinib in the form Tablet 40 mg (as fumarate) *[Maximum Quantity: 84; Number of Repeats: 0]*
2. *omit from the column headed “Circumstances”:* C13166 *substitute:* C15526
3. *omit from the column headed “Purposes”:* P13166 *substitute:* P15526
4. Schedule 1, Part 1, entry for Gilteritinib in the form Tablet 40 mg (as fumarate) *[Maximum Quantity: 84; Number of Repeats: 4]*
5. *omit from the column headed “Circumstances”:* C13242 *substitute:* C15466
6. *omit from the column headed “Purposes”:* P13242 *substitute:* P15466
7. Schedule 1, Part 1, omit entry for Glucose indicator-urine
8. Schedule 1, Part 1, entry for Insulin neutral with insulin isophane in the form Injections (human), cartridges, 30 units-70 units per mL, 3 mL, 5
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Insulin neutral with insulin isophane | Injections (human), cartridges, 30 units-70 units per mL, 3 mL, 5 | Injection | Mixtard 30/70 InnoLet | NI | MP NP |  |  | 5 | 1 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Ipratropium in the form Nebuliser solution containing ipratropium bromide 250 micrograms (as monohydrate) in 1 mL single dose units, 30
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ipratropium | Nebuliser solution containing ipratropium bromide 250 micrograms (as monohydrate) in 1 mL single dose units, 30 | Inhalation | Aeron 250 | AL | MP NP | C6331 C6341 |  | 2 | 5 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Ipratropium in the form Nebuliser solution containing ipratropium bromide 500 micrograms (as monohydrate) in 1 mL single dose units, 30
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ipratropium | Nebuliser solution containing ipratropium bromide 500 micrograms (as monohydrate) in 1 mL single dose units, 30 | Inhalation | Aeron 500 | AL | MP NP | C6331 C6341 |  | 2 | 5 |  | 1 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Larotrectinib | Capsule 25 mg (as sulfate) | Oral | Vitrakvi | BN | MP | C12981 C12982 C15467 | P12981 P12982 P15467 | 56 | 2 |  | 56 |  |  |
| Larotrectinib | Capsule 25 mg (as sulfate) | Oral | Vitrakvi | BN | MP | C12980 C15509 | P12980 P15509 | 56 | 5 |  | 56 |  |  |
| Larotrectinib | Capsule 100 mg (as sulfate) | Oral | Vitrakvi | BN | MP | C12981 C12982 C15467 | P12981 P12982 P15467 | 56 | 2 |  | 56 |  |  |
| Larotrectinib | Capsule 100 mg (as sulfate) | Oral | Vitrakvi | BN | MP | C12980 C15509 | P12980 P15509 | 56 | 5 |  | 56 |  |  |
| Larotrectinib | Oral solution 20 mg per mL (as sulfate), 50 mL, 2 | Oral | Vitrakvi | BN | MP | C12981 C12982 C15467 | P12981 P12982 P15467 | 1 | 2 |  | 1 |  |  |
| Larotrectinib | Oral solution 20 mg per mL (as sulfate), 50 mL, 2 | Oral | Vitrakvi | BN | MP | C12980 C15509 | P12980 P15509 | 1 | 5 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Lenvatinib in the form Capsule 4 mg (as mesilate) *[Maximum Quantity: 30; Number of Repeats: 2]*
2. *omit from the column headed “Circumstances”:* **C6604**
3. *insert in numerical order in the column headed “Circumstances”:* **C15510**
4. *omit from the column headed “Purposes”:* **P6604**
5. *insert in numerical order in the column headed “Purposes”:* **P15510**
6. Schedule 1, Part 1, entry for Lenvatinib in the form Capsule 10 mg (as mesilate)
7. *omit from the column headed “Circumstances”:* **C6604**
8. *insert in numerical order in the column headed “Circumstances”:* **C15510**
9. Schedule 1, Part 1, entry for Mepolizumab
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Mepolizumab | Powder for injection 100 mg | Injection | Nucala | GK | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |

1. Schedule 1, Part 1, entry for Metformin in the form Tablet (extended release) containing metformin hydrochloride 500 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Metformin | Tablet (extended release) containing metformin hydrochloride 500 mg | Oral | Blooms the Chemist Metformin XR 500 | IB | MP NP |  |  | 120 | 5 |  | 120 |  |  |
| Metformin | Tablet (extended release) containing metformin hydrochloride 500 mg | Oral | Blooms the Chemist Metformin XR 500 | IB | MP NP |  | P14238 | 240 | 5 |  | 120 |  |  |

1. Schedule 1, Part 1, entry for Metformin in the form Tablet (extended release) containing metformin hydrochloride 1 g
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Metformin | Tablet (extended release) containing metformin hydrochloride 1 g | Oral | Blooms the Chemist Metformin XR 1000 | IB | MP NP |  |  | 60 | 5 |  | 60 |  |  |
| Metformin | Tablet (extended release) containing metformin hydrochloride 1 g | Oral | Blooms the Chemist Metformin XR 1000 | IB | MP NP |  | P14238 | 120 | 5 |  | 60 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Methotrexate | Injection 5 mg in 2 mL vial | Injection | DBL Methotrexate | PF | MP NP |  |  | 5 | 0 |  | 5 |  |  |
| Methotrexate | Injection 7.5 mg in 0.15 mL pre-filled syringe | Injection | Trexject | LM | MP NP | C7488 C7518 |  | 4 | 5 |  | 1 |  |  |
| Methotrexate | Injection 7.5 mg in 0.15 mL pre-filled syringe | Injection | Trexject | LM | MP | C15068 |  | 4 | 5 |  | 1 |  |  |
| Methotrexate | Injection 10 mg in 0.2 mL pre-filled syringe | Injection | Trexject | LM | MP NP | C7488 C7518 |  | 4 | 5 |  | 1 |  |  |
| Methotrexate | Injection 10 mg in 0.2 mL pre-filled syringe | Injection | Trexject | LM | MP | C15068 |  | 4 | 5 |  | 1 |  |  |
| Methotrexate | Injection 15 mg in 0.3 mL pre-filled syringe | Injection | Trexject | LM | MP NP | C7488 C7518 |  | 4 | 5 |  | 1 |  |  |
| Methotrexate | Injection 15 mg in 0.3 mL pre-filled syringe | Injection | Trexject | LM | MP | C15068 |  | 4 | 5 |  | 1 |  |  |
| Methotrexate | Injection 20 mg in 0.4 mL pre-filled syringe | Injection | Trexject | LM | MP NP | C7488 C7518 |  | 4 | 5 |  | 1 |  |  |
| Methotrexate | Injection 20 mg in 0.4 mL pre-filled syringe | Injection | Trexject | LM | MP | C15068 |  | 4 | 5 |  | 1 |  |  |
| Methotrexate | Injection 25 mg in 0.5 mL pre-filled syringe | Injection | Trexject | LM | MP NP | C7488 C7518 |  | 4 | 5 |  | 1 |  |  |
| Methotrexate | Injection 25 mg in 0.5 mL pre-filled syringe | Injection | Trexject | LM | MP | C15068 |  | 4 | 5 |  | 1 |  |  |
| Methotrexate | Injection 50 mg in 2 mL vial | Injection | DBL Methotrexate | PF | MP NP |  |  | 5 | 5 |  | 5 |  |  |
| Methotrexate | Injection 50 mg in 2 mL vial | Injection | DBL Methotrexate | PF | MP |  | P14238 | 10 | 5 |  | 5 |  |  |
| Methotrexate | Solution concentrate for I.V. infusion 500 mg in 20 mL vial | Injection | DBL Methotrexate | PF | MP |  | P6276 | See Note 3 | See Note 3 |  | 1 |  | PB(100) |
| Methotrexate | Solution concentrate for I.V. infusion 1000 mg in 10 mL vial | Injection | DBL Methotrexate | PF | MP |  | P6276 | See Note 3 | See Note 3 |  | 1 |  | PB(100) |
| Methotrexate | Solution concentrate for I.V. infusion 1000 mg in 10 mL vial | Injection | Methotrexate Accord | OD | MP |  | P6276 | See Note 3 | See Note 3 |  | 1 |  | PB(100) |
| Methotrexate | Solution concentrate for I.V. infusion 5000 mg in 50 mL vial | Injection | Methotrexate Ebewe | SZ | MP |  | P6276 | See Note 3 | See Note 3 |  | 1 |  | PB(100) |
| Methotrexate | Tablet 2.5 mg | Oral | ARX-Methotrexate | XT | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Methotrexate | Tablet 2.5 mg | Oral | Chexate | OX | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Methotrexate | Tablet 2.5 mg | Oral | Methoblastin | PF | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Methotrexate | Tablet 10 mg | Oral | ARX-Methotrexate | XT | MP NP |  |  | 15 | 3 |  | 15 |  |  |
| Methotrexate | Tablet 10 mg | Oral | ARX-Methotrexate | XT | MP NP |  | P5648 | 50 | 2 |  | 50 |  |  |
| Methotrexate | Tablet 10 mg | Oral | Chexate | OX | MP NP |  |  | 15 | 3 |  | 15 |  |  |
| Methotrexate | Tablet 10 mg | Oral | Chexate | OX | MP NP |  | P5648 | 50 | 2 |  | 50 |  |  |
| Methotrexate | Tablet 10 mg | Oral | Methoblastin | PF | MP NP |  |  | 15 | 3 |  | 15 |  |  |
| Methotrexate | Tablet 10 mg | Oral | Methoblastin | PF | MP NP |  | P5648 | 50 | 2 |  | 50 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Metoclopramide | Injection containing 10 mg metoclopramide hydrochloride (as monohydrate) in 2 mL | Injection | Metoclopramide HCI Medsurge | DZ | MP NP MW PDP |  |  | 10 | 0 |  | 10 |  |  |
| Metoclopramide | Injection containing 10 mg metoclopramide hydrochloride (as monohydrate) in 2 mL | Injection | Metoclopramide HCI Medsurge | DZ | MP NP |  | P6084 | 40 CN6084 | 2 CN6084 |  | 10 |  |  |
| Metoclopramide | Injection containing 10 mg metoclopramide hydrochloride (as monohydrate) in 2 mL | Injection | METOCLOPRAMIDE INJECTION BP | WZ | MP NP MW PDP |  |  | 10 | 0 |  | 10 |  |  |
| Metoclopramide | Injection containing 10 mg metoclopramide hydrochloride (as monohydrate) in 2 mL | Injection | METOCLOPRAMIDE INJECTION BP | WZ | MP NP |  | P6084 | 40 CN6084 | 2 CN6084 |  | 10 |  |  |
| Metoclopramide | Tablet containing 10 mg metoclopramide hydrochloride (as monohydrate) | Oral | APO-Metoclopramide | TX | MP NP MW PDP |  |  | 25 | 0 |  | 25 |  |  |
| Metoclopramide | Tablet containing 10 mg metoclopramide hydrochloride (as monohydrate) | Oral | APO-Metoclopramide | TX | MP NP |  |  | 100 | 5 |  | 25 |  |  |
| Metoclopramide | Tablet containing 10 mg metoclopramide hydrochloride (as monohydrate) | Oral | EMEXLON | RW | MP NP MW PDP |  |  | 25 | 0 |  | 25 |  |  |
| Metoclopramide | Tablet containing 10 mg metoclopramide hydrochloride (as monohydrate) | Oral | EMEXLON | RW | MP NP |  |  | 100 | 5 |  | 25 |  |  |
| Metoclopramide | Tablet containing 10 mg metoclopramide hydrochloride (as monohydrate) | Oral | Maxolon | IL | MP NP MW PDP |  |  | 25 | 0 |  | 25 |  |  |
| Metoclopramide | Tablet containing 10 mg metoclopramide hydrochloride (as monohydrate) | Oral | Maxolon | IL | MP NP |  |  | 100 | 5 |  | 25 |  |  |
| Metoclopramide | Tablet containing 10 mg metoclopramide hydrochloride (as monohydrate) | Oral | Pramin | AF | MP NP MW PDP |  |  | 25 | 0 |  | 25 |  |  |
| Metoclopramide | Tablet containing 10 mg metoclopramide hydrochloride (as monohydrate) | Oral | Pramin | AF | MP NP |  |  | 100 | 5 |  | 25 |  |  |

1. Schedule 1, Part 1, entry for Midazolam
   1. *omit from the column headed “Section 100/ Prescriber Bag only”:* **D(MP) D(NP)** *substitute:* **PB(MP) PB(NP)**
2. Schedule 1, Part 1, after entry for Midazolam
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Midazolam | Oromucosal solution (as maleate) 5 mg in 0.5 mL single use pre-filled oral syringe | Buccal | Zyamis | IX | MP NP | C15456 |  | 2 | 1 | V15456 | 1 |  |  |
| Midazolam | Oromucosal solution (as maleate) 5 mg in 0.5 mL single use pre-filled oral syringe | Buccal | Zyamis | IX | MP | C15457 |  | 2 | 1 | V15457 | 1 |  |  |
| Midazolam | Oromucosal solution (as maleate) 7.5 mg in 0.75 mL single use pre-filled oral syringe | Buccal | Zyamis | IX | MP NP | C15456 |  | 2 | 1 | V15456 | 1 |  |  |
| Midazolam | Oromucosal solution (as maleate) 7.5 mg in 0.75 mL single use pre-filled oral syringe | Buccal | Zyamis | IX | MP | C15457 |  | 2 | 1 | V15457 | 1 |  |  |
| Midazolam | Oromucosal solution (as maleate) 10 mg in 1 mL single use pre-filled oral syringe | Buccal | Zyamis | IX | MP NP | C15456 |  | 2 | 1 | V15456 | 1 |  |  |
| Midazolam | Oromucosal solution (as maleate) 10 mg in 1 mL single use pre-filled oral syringe | Buccal | Zyamis | IX | MP | C15457 |  | 2 | 1 | V15457 | 1 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Mitozantrone | Injection 25 mg (as hydrochloride) in 12.5 mL | Injection | Onkotrone | BX | MP |  |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

1. Schedule 1, Part 1, after entry for Montelukast in the form Tablet, chewable, 4 mg (as sodium) *[Brand: Montelukast Sandoz 4]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Montelukast | Tablet, chewable, 4 mg (as sodium) | Oral | Montelukast Viatris | AL | MP NP | C6666 |  | 28 | 5 |  | 28 |  |  |

1. Schedule 1, Part 1, entry for Mycophenolic acid in the form Capsule containing mycophenolate mofetil 250 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Mycophenolic acid | Capsule containing mycophenolate mofetil 250 mg | Oral | CellCept | RO | MP |  |  | 300 | 5 |  | 100 |  |  |
| Mycophenolic acid | Capsule containing mycophenolate mofetil 250 mg | Oral | CellCept | RO | MP |  | P14238 | 600 | 5 |  | 100 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Mycophenolic acid | Tablet containing mycophenolate mofetil 500 mg | Oral | CellCept | RO | MP |  |  | 150 | 5 |  | 50 |  |  |
| Mycophenolic acid | Tablet containing mycophenolate mofetil 500 mg | Oral | CellCept | RO | MP |  | P14238 | 300 | 5 |  | 50 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Niraparib | Capsule 100 mg (as tosilate monohydrate) | Oral | Zejula | GK | MP | C15230 C15239 | P15230 P15239 | 56 | 2 |  | 56 |  |  |
| Niraparib | Capsule 100 mg (as tosilate monohydrate) | Oral | Zejula | GK | MP | C15160 C15203 | P15160 P15203 | 56 | 5 |  | 56 |  |  |
| Niraparib | Capsule 100 mg (as tosilate monohydrate) | Oral | Zejula | GK | MP | C15108 C15162 | P15108 P15162 | 84 | 2 |  | 84 |  |  |
| Niraparib | Capsule 100 mg (as tosilate monohydrate) | Oral | Zejula | GK | MP | C15155 C15181 | P15155 P15181 | 84 | 5 |  | 84 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Nivolumab | Injection concentrate for I.V. infusion 40 mg in 4 mL | Injection | Opdivo | BQ | MP | C9216 C9252 C9298 C9299 C9312 C9321 C10119 C10120 C11468 C11477 C11985 C13433 C13445 C13839 C13900 C14001 C14676 C14816 C14830 C15471 C15527 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Nivolumab | Injection concentrate for I.V. infusion 100 mg in 10 mL | Injection | Opdivo | BQ | MP | C9216 C9252 C9298 C9299 C9312 C9321 C10119 C10120 C11468 C11477 C11985 C13433 C13445 C13839 C13900 C14001 C14676 C14816 C14830 C15471 C15527 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

1. Schedule 1, Part 1, omit entry for Oxprenolol
2. Schedule 1, Part 1, entry for Oxycodone in the form Capsule containing oxycodone hydrochloride 5 mg
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Oxycodone | Capsule containing oxycodone hydrochloride 5 mg | Oral | Oxycodone BNM | BZ | PDP | C10768 | P10768 | 20 | 0 |  | 20 |  |  |
| Oxycodone | Capsule containing oxycodone hydrochloride 5 mg | Oral | Oxycodone BNM | BZ | MP NP | C10764 C10771 C10772 | P10764 P10771 P10772 | 20 | 0 | V10764 V10771 V10772 | 20 |  |  |
| Oxycodone | Capsule containing oxycodone hydrochloride 5 mg | Oral | OxyNorm | MF | MP NP PDP | C10766 | P10766 | 10 | 0 |  | 10 |  |  |
| Oxycodone | Capsule containing oxycodone hydrochloride 5 mg | Oral | OxyNorm | MF | PDP | C10768 | P10768 | 20 | 0 |  | 20 |  |  |
| Oxycodone | Capsule containing oxycodone hydrochloride 5 mg | Oral | OxyNorm | MF | MP NP | C10764 C10771 C10772 | P10764 P10771 P10772 | 20 | 0 | V10764 V10771 V10772 | 20 |  |  |

1. Schedule 1, Part 1, entry for Oxycodone in the form Capsule containing oxycodone hydrochloride 10 mg
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Oxycodone | Capsule containing oxycodone hydrochloride 10 mg | Oral | Oxycodone BNM | BZ | MP NP PDP | C10766 | P10766 | 10 | 0 |  | 20 |  |  |
| Oxycodone | Capsule containing oxycodone hydrochloride 10 mg | Oral | Oxycodone BNM | BZ | MP NP | C10764 C10771 C10772 | P10764 P10771 P10772 | 20 | 0 | V10764 V10771 V10772 | 20 |  |  |
| Oxycodone | Capsule containing oxycodone hydrochloride 10 mg | Oral | Oxycodone BNM | BZ | PDP | C10768 | P10768 | 20 | 0 |  | 20 |  |  |
| Oxycodone | Capsule containing oxycodone hydrochloride 10 mg | Oral | OxyNorm | MF | MP NP PDP | C10766 | P10766 | 10 | 0 |  | 20 |  |  |
| Oxycodone | Capsule containing oxycodone hydrochloride 10 mg | Oral | OxyNorm | MF | MP NP | C10764 C10771 C10772 | P10764 P10771 P10772 | 20 | 0 | V10764 V10771 V10772 | 20 |  |  |
| Oxycodone | Capsule containing oxycodone hydrochloride 10 mg | Oral | OxyNorm | MF | PDP | C10768 | P10768 | 20 | 0 |  | 20 |  |  |

1. Schedule 1, Part 1, entry for Oxycodone in the form Capsule containing oxycodone hydrochloride 20 mg
   1. *insert as first entry:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Oxycodone | Capsule containing oxycodone hydrochloride 20 mg | Oral | Oxycodone BNM | BZ | MP NP | C10764 C10771 C10772 |  | 20 | 0 | V10764 V10771 V10772 | 20 |  |  |

1. Schedule 1, Part 1, after entry for Patiromer in the form Powder for oral suspension 16.8 g *[Authorised Prescriber: MP; Maximum Quantity: 30; Number of Repeats: 5]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Patisiran | Solution concentrate for I.V. infusion 10 mg in 5 mL | Injection | Onpattro | WM | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |

1. Schedule 1, Part 1, after entry for Permethrin
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Permethrin | Cream 50 mg per g, 60 g (S19A) | Application | Permethrin Cream 5% w/w (Encube Ethicals, USA) | RQ | MP NP |  |  | 1 | 0 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Pregabalin in the form Capsule 25 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pregabalin | Capsule 25 mg | Oral | Cipla Pregabalin | LR | MP NP | C4172 |  | 56 | 5 |  | 56 |  |  |

1. Schedule 1, Part 1, entry for Pregabalin in the form Capsule 75 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pregabalin | Capsule 75 mg | Oral | Cipla Pregabalin | LR | MP NP | C4172 |  | 56 | 5 |  | 56 |  |  |

1. Schedule 1, Part 1, entry for Pregabalin in the form Capsule 300 mg
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pregabalin | Capsule 300 mg | Oral | Cipla Pregabalin | LR | MP NP | C4172 |  | 56 | 5 |  | 56 |  |  |

1. Schedule 1, Part 1, entry for Protein hydrolysate formula with medium chain triglycerides
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Protein hydrolysate formula with medium chain triglycerides | Oral powder 400 g (Alfaré) | Oral | Alfaré | NT | MP NP | C6137 C6138 C6148 C6157 C6158 C6166 C6174 C6182 C6193 C6194 C6195 C6204 C6205 C6206 |  | 8 | 5 |  | 1 |  |  |

1. Schedule 1, Part 1, entry for Quetiapine in the form Tablet (modified release) 50 mg (as fumarate)
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Quetiapine | Tablet (modified release) 50 mg (as fumarate) | Oral | APX-Quetiapine XR | TY | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 50 mg (as fumarate) | Oral | QUETIAPINE-AS XR | RW | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 50 mg (as fumarate) | Oral | Quetiapine Sandoz XR | SZ | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 50 mg (as fumarate) | Oral | Quetia XR | OW | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 50 mg (as fumarate) | Oral | Seroquel XR | AL | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 50 mg (as fumarate) | Oral | Tevatiapine XR | TB | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |

1. Schedule 1, Part 1, entry for Quetiapine in the form Tablet (modified release) 200 mg (as fumarate)
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Quetiapine | Tablet (modified release) 200 mg (as fumarate) | Oral | APX-Quetiapine XR | TY | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 200 mg (as fumarate) | Oral | QUETIAPINE-AS XR | RW | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 200 mg (as fumarate) | Oral | Quetiapine Sandoz XR | SZ | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 200 mg (as fumarate) | Oral | Quetia XR | OW | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 200 mg (as fumarate) | Oral | Seroquel XR | AL | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 200 mg (as fumarate) | Oral | Tevatiapine XR | TB | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |

1. Schedule 1, Part 1, entry for Quetiapine in the form Tablet (modified release) 300 mg (as fumarate)
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Quetiapine | Tablet (modified release) 300 mg (as fumarate) | Oral | APX-Quetiapine XR | TY | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 300 mg (as fumarate) | Oral | QUETIAPINE-AS XR | RW | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 300 mg (as fumarate) | Oral | Quetiapine Sandoz XR | SZ | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 300 mg (as fumarate) | Oral | Quetia XR | OW | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 300 mg (as fumarate) | Oral | Seroquel XR | AL | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 300 mg (as fumarate) | Oral | Tevatiapine XR | TB | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |

1. Schedule 1, Part 1, entry for Quetiapine in the form Tablet (modified release) 400 mg (as fumarate)
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Quetiapine | Tablet (modified release) 400 mg (as fumarate) | Oral | APX-Quetiapine XR | TY | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 400 mg (as fumarate) | Oral | QUETIAPINE-AS XR | RW | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 400 mg (as fumarate) | Oral | Quetiapine Sandoz XR | SZ | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 400 mg (as fumarate) | Oral | Quetia XR | OW | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 400 mg (as fumarate) | Oral | Seroquel XR | AL | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |
| Quetiapine | Tablet (modified release) 400 mg (as fumarate) | Oral | Tevatiapine XR | TB | MP NP | C4246 C5611 C5639 |  | 60 | 5 |  | 60 |  |  |

1. Schedule 1, Part 1, after entry for Ramipril in the form Tablet 10 mg *[Brand: Ramipril Sandoz; Maximum Quantity: 60; Number of Repeats: 5]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ramipril | Tablet 10 mg | Oral | Ramipril Viatris | AL | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ramipril | Tablet 10 mg | Oral | Ramipril Viatris | AL | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ribavirin | Tablet 200 mg | Oral | Ibavyr | IX | MP NP | C5957 |  | 200 | 2 |  | 100 |  | C(100) |

1. Schedule 1, Part 1, entry for Risperidone in each of the forms: Tablet 3 mg; and Tablet 4 mg
   1. *omit from the column headed “Purposes” (all instances):* **P4246 P5907**
2. Schedule 1, Part 1, entry for Roxithromycin in the form Tablet 150 mg *[Brand: APO-Roxithromycin; Maximum Quantity: 10; Number of Repeats: 0]*
3. *omit from the column headed “Authorised Prescriber”:* **MP NP** *substitute:* **MP NP PDP**
4. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Roxithromycin | Tablet 150 mg | Oral | APO-Roxithromycin | TX | PDP |  |  | 10 | 0 |  | 10 |  |  |

1. Schedule 1, Part 1, entry for Roxithromycin in the form Tablet 150 mg *[Brand: APX-Roxithromycin; Maximum Quantity: 10; Number of Repeats: 0]*
2. *omit from the column headed “Authorised Prescriber”:* **MP NP** *substitute:* **MP NP PDP**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Roxithromycin | Tablet 150 mg | Oral | APX-Roxithromycin | TY | PDP |  |  | 10 | 0 |  | 10 |  |  |

1. Schedule 1, Part 1, entry for Roxithromycin in the form Tablet 150 mg *[Brand: Roxar 150; Maximum Quantity: 10; Number of Repeats: 0]*
2. *omit from the column headed “Authorised Prescriber”:* **MP NP** *substitute:* **MP NP PDP**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Roxithromycin | Tablet 150 mg | Oral | Roxar 150 | RW | PDP |  |  | 10 | 0 |  | 10 |  |  |

1. Schedule 1, Part 1, entry for Roxithromycin in the form Tablet 150 mg *[Brand:* *Roxithromycin Sandoz; Maximum Quantity: 10; Number of Repeats: 0]*
2. *omit from the column headed “Authorised Prescriber”:* **MP NP** *substitute:* **MP NP PDP**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Roxithromycin | Tablet 150 mg | Oral | Roxithromycin Sandoz | SZ | PDP |  |  | 10 | 0 |  | 10 |  |  |

1. Schedule 1, Part 1, entry for Roxithromycin in the form Tablet 300 mg *[Brand: APO-Roxithromycin; Maximum Quantity: 5; Number of Repeats: 0]*
2. *omit from the column headed “Authorised Prescriber”:* **MP NP** *substitute:* **MP NP PDP**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Roxithromycin | Tablet 300 mg | Oral | APO-Roxithromycin | TX | PDP |  |  | 5 | 0 |  | 5 |  |  |

1. Schedule 1, Part 1, entry for Roxithromycin in the form Tablet 300 mg *[Brand: APX-Roxithromycin; Maximum Quantity: 5; Number of Repeats: 0]*
2. *omit from the column headed “Authorised Prescriber”:* **MP NP** *substitute:* **MP NP PDP**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Roxithromycin | Tablet 300 mg | Oral | APX-Roxithromycin | TY | PDP |  |  | 5 | 0 |  | 5 |  |  |

1. Schedule 1, Part 1, entry for Roxithromycin in the form Tablet 300 mg *[Brand: Roxar 300; Maximum Quantity: 5; Number of Repeats: 0]*
2. *omit from the column headed “Authorised Prescriber”:* **MP NP** *substitute:* **MP NP PDP**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Roxithromycin | Tablet 300 mg | Oral | Roxar 300 | RW | PDP |  |  | 5 | 0 |  | 5 |  |  |

1. Schedule 1, Part 1, entry for Roxithromycin in the form Tablet 300 mg *[Brand: Roxithromycin Sandoz; Maximum Quantity: 5; Number of Repeats: 0]*
2. *omit from the column headed “Authorised Prescriber”:* **MP NP** *substitute:* **MP NP PDP**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Roxithromycin | Tablet 300 mg | Oral | Roxithromycin Sandoz | SZ | PDP |  |  | 5 | 0 |  | 5 |  |  |

1. Schedule 1, Part 1, after entry for Selinexor in the form Tablet 20 mg *[Pack Quantity: 32]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Selumetinib | Capsule 10 mg | Oral | Koselugo | XI | MP | C15477 C15490 C15491 |  | 60 | 5 |  | 60 |  |  |
| Selumetinib | Capsule 25 mg | Oral | Koselugo | XI | MP | C15477 C15490 C15491 |  | 60 | 5 |  | 60 |  |  |

1. Schedule 1, Part 1, after entry for Sertraline in the form Tablet 50 mg (as hydrochloride) *[Brand: APO-Sertraline]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sertraline | Tablet 50 mg (as hydrochloride) | Oral | Blooms The Chemist Sertraline | BG | MP NP | C4755 C6277 C6289 |  | 30 | 5 |  | 30 |  |  |

1. Schedule 1, Part 1, after entry for Sertraline in the form Tablet 100 mg (as hydrochloride) *[Brand: APO-Sertraline]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sertraline | Tablet 100 mg (as hydrochloride) | Oral | Blooms The Chemist Sertraline | BG | MP NP | C4755 C6277 C6289 |  | 30 | 5 |  | 30 |  |  |

1. Schedule 1, Part 1, entry for Sofosbuvir with velpatasvir
   1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sofosbuvir with velpatasvir | Tablet containing 400 mg sofosbuvir with 100 mg velpatasvir | Oral | Epclusa | GI | MP NP | C5969 |  | 28 | 2 |  | 28 |  | C(100) |

1. Schedule 1, Part 1, after entry for Tadalafil in the form Tablet 20 mg *[Brand: TADALIS 20]*
   1. *insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Tadalafil | Tablet 20 mg | Oral | Tadalis 20 | LR | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 60 |  | D(100) |

1. Schedule 1, Part 1, omit entries for Tafluprost
2. Schedule 1, Part 1, entry for Tenofovir
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Tenofovir | Tablet containing tenofovir disoproxil fumarate 300 mg | Oral | Tenofovir APOTEX | TX | MP NP | C10362 | P10362 | 60 | 2 |  | 30 |  | D(100) |
| Tenofovir | Tablet containing tenofovir disoproxil fumarate 300 mg | Oral | Tenofovir APOTEX | TX | MP NP | C6980 C6982 C6983 C6984 C6992 C6998 | P6980 P6982 P6983 P6984 P6992 P6998 | 60 | 5 |  | 30 |  | D(100) |
| Tenofovir | Tablet containing tenofovir disoproxil fumarate 300 mg | Oral | TENOFOVIR ARX | XT | MP NP | C10362 | P10362 | 60 | 2 |  | 30 |  | D(100) |
| Tenofovir | Tablet containing tenofovir disoproxil fumarate 300 mg | Oral | TENOFOVIR ARX | XT | MP NP | C6980 C6982 C6983 C6984 C6992 C6998 | P6980 P6982 P6983 P6984 P6992 P6998 | 60 | 5 |  | 30 |  | D(100) |
| Tenofovir | Tablet containing tenofovir disoproxil fumarate 300 mg | Oral | Tenofovir Sandoz | SZ | MP NP | C10362 | P10362 | 60 | 2 |  | 30 |  | D(100) |
| Tenofovir | Tablet containing tenofovir disoproxil fumarate 300 mg | Oral | Tenofovir Sandoz | SZ | MP NP | C6980 C6982 C6983 C6984 C6992 C6998 | P6980 P6982 P6983 P6984 P6992 P6998 | 60 | 5 |  | 30 |  | D(100) |
| Tenofovir | Tablet containing tenofovir disoproxil fumarate 300 mg | Oral | Viread | GI | MP NP | C10362 | P10362 | 60 | 2 |  | 30 |  | D(100) |
| Tenofovir | Tablet containing tenofovir disoproxil fumarate 300 mg | Oral | Viread | GI | MP NP | C6980 C6982 C6983 C6984 C6992 C6998 | P6980 P6982 P6983 P6984 P6992 P6998 | 60 | 5 |  | 30 |  | D(100) |
| Tenofovir | Tablet containing tenofovir disoproxil maleate 300 mg | Oral | Tenofovir Disoproxil Mylan | AF | MP NP | C10362 | P10362 | 60 | 2 |  | 30 |  | D(100) |
| Tenofovir | Tablet containing tenofovir disoproxil maleate 300 mg | Oral | Tenofovir Disoproxil Mylan | AF | MP NP | C6980 C6982 C6983 C6984 C6992 C6998 | P6980 P6982 P6983 P6984 P6992 P6998 | 60 | 5 |  | 30 |  | D(100) |
| Tenofovir | Tablet containing tenofovir disoproxil maleate 300 mg | Oral | Tenofovir Disoproxil Viatris | AL | MP NP | C10362 | P10362 | 60 | 2 |  | 30 |  | D(100) |
| Tenofovir | Tablet containing tenofovir disoproxil maleate 300 mg | Oral | Tenofovir Disoproxil Viatris | AL | MP NP | C6980 C6982 C6983 C6984 C6992 C6998 | P6980 P6982 P6983 P6984 P6992 P6998 | 60 | 5 |  | 30 |  | D(100) |
| Tenofovir | Tablet containing tenofovir disoproxil phosphate 291 mg | Oral | Tenofovir GH | GQ | MP NP | C10362 | P10362 | 60 | 2 |  | 30 |  | D(100) |
| Tenofovir | Tablet containing tenofovir disoproxil phosphate 291 mg | Oral | Tenofovir GH | GQ | MP NP | C6980 C6982 C6983 C6984 C6992 C6998 | P6980 P6982 P6983 P6984 P6992 P6998 | 60 | 5 |  | 30 |  | D(100) |

1. Schedule 1, Part 1, after entry for Teriparatide in the form Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen *[Brand: Terrosa]*
   1. *insert:*

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

1. Schedule 1, Part 1, after entry for Testosterone in the form I.M. injection containing testosterone undecanoate 1,000 mg in 4 mL *[Brand: Reandron 1000]*
   1. *insert:*

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

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Timolol | Eye drops 5 mg (as maleate) per mL, 5 mL | Application to the eye | Timoptol | MF | MP AO |  |  | 1 | 5 |  | 1 |  |  |
| Timolol | Eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL | Application to the eye | Timoptol XE | MF | MP AO |  |  | 1 | 5 |  | 1 |  |  |
| Timolol | Eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL (S19A) | Application to the eye | Timoptol XE 0.50% (South Africa) | LM | MP AO |  |  | 1 | 5 |  | 1 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Valganciclovir | Powder for oral solution 50 mg (as hydrochloride) per mL, 100 mL | Oral | Valcyte | PB | MP NP | C4980 |  | 11 | 5 |  | 1 |  | D(100) |
| Valganciclovir | Powder for oral solution 50 mg (as hydrochloride) per mL, 100 mL | Oral | Valcyte | PB | MP | C4989 C9316 |  | 11 | 5 |  | 1 |  | D(100) |
| Valganciclovir | Tablet 450 mg (as hydrochloride) | Oral | Valganciclovir Sandoz | SZ | MP NP | C4980 |  | 120 | 5 |  | 60 |  | D(100) |
| Valganciclovir | Tablet 450 mg (as hydrochloride) | Oral | Valganciclovir Sandoz | SZ | MP | C4989 C9316 |  | 120 | 5 |  | 60 |  | D(100) |
| Valganciclovir | Tablet 450 mg (as hydrochloride) | Oral | Valganciclovir Viatris | AL | MP NP | C4980 |  | 120 | 5 |  | 60 |  | D(100) |
| Valganciclovir | Tablet 450 mg (as hydrochloride) | Oral | Valganciclovir Viatris | AL | MP | C4989 C9316 |  | 120 | 5 |  | 60 |  | D(100) |

1. Schedule 1, Part 1, entry for Zoledronic acid in the form Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL
   1. *substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Zoledronic acid | Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL | Injection | APO-Zoledronic Acid | TX | MP | C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328 |  | 1 | 11 |  | 1 |  | PB(100) |
| Zoledronic acid | Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL | Injection | DEZTRON | DZ | MP | C14729 C14735 | P14729 P14735 | 1 | 0 |  | 1 |  | PB(100) |
| Zoledronic acid | Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL | Injection | DEZTRON | DZ | MP | C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328 | P5605 P5703 P5704 P5735 P9268 P9304 P9317 P9328 | 1 | 11 |  | 1 |  | PB(100) |
| Zoledronic acid | Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL | Injection | Zoledronate-DRLA 4 | RZ | MP | C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328 |  | 1 | 11 |  | 1 |  | PB(100) |
| Zoledronic acid | Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL | Injection | Zoledronic Acid Accord | OC | MP | C14729 C14735 | P14729 P14735 | 1 | 0 |  | 1 |  | PB(100) |
| Zoledronic acid | Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL | Injection | Zoledronic Acid Accord | OC | MP | C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328 | P5605 P5703 P5704 P5735 P9268 P9304 P9317 P9328 | 1 | 11 |  | 1 |  | PB(100) |
| Zoledronic acid | Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL | Injection | Zometa | SA | MP | C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328 |  | 1 | 11 |  | 1 |  | PB(100) |

1. Schedule 1, Part 2, after entry for Acalabrutinib
   1. *insert:*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Alirocumab | Injection 75 mg in 1 mL single use pre‑filled pen | Injection | Praluent | SW | 2 |  |  |
| Alirocumab | Injection 150 mg in 1 mL single use pre‑filled pen | Injection | Praluent | SW | 2 |  |  |
| Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides | Oral powder 400 g (Alfamino) | Oral | Alfamino | NT | 1 |  |  |

1. Schedule 1, Part 2, entry for Fluorometholone
   1. *substitute:*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Fluorometholone | Eye drops 1 mg per mL, 5 mL | Application to the eye | FML Liquifilm | VE | 1 |  |  |

1. Schedule 1, Part 2, after entry for Fluorometholone
   1. *insert:*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Glucose indicator-urine | Test strips, 50 (Diastix) | For external use | Diastix | DX | 1 |  |  |

1. Schedule 1, Part 2, after entry for Ketoconazole
   1. *insert:*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Mepolizumab | Powder for injection 100 mg | Injection | Nucala | GK | 1 |  |  |
| Niraparib | Capsule 100 mg (as tosilate monohydrate) | Orald | Zejula | GK | 56 |  |  |
| Niraparib | Capsule 100 mg (as tosilate monohydrate) | Oral | Zejula | GK | 84 |  |  |
| Protein hydrolysate formula with medium chain triglycerides | Oral powder 400 g (Alfaré) | Oral | Alfaré | NT | 1 |  |  |

1. Schedule 1, Part 2, omit entries for Raltegravir
2. Schedule 3
   1. *omit:*

|  |  |  |
| --- | --- | --- |
| GG | Gem Pharma Pty Ltd | 45 641 456 868 |

1. Schedule 4, Part 1, entry for Circumstances Code “C5533”

*omit from the column headed “Listed Drug”:* **Amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexanoic acid***substitute:* **Amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid**

1. Schedule 4, Part 1, entry for Circumstances Code “C5534”

*omit from the column headed “Listed Drug”:* **Amino acid formula with fat, carbohydrate, vitamins, minerals, and trace elements, without methionine and supplemented with docosahexanoic acid***substitute:* **Amino acid formula with fat, carbohydrate, vitamins, minerals, and trace elements, without methionine and supplemented with docosahexaenoic acid**

1. Schedule 4, Part 1, entry for Circumstances Code “C5571”

*omit from the column headed “Listed Drug”:* **Amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexanoic acid***substitute:* **Amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexaenoic acid**

1. Schedule 4, Part 1, entry for Circumstances Code “C5852”

*omit from the column headed “Listed Drug”:* Glucose indicator-urine

1. Schedule 4, Part 1, omit entry for Circumstances Code “C6206”
2. Schedule 4, Part 1, omit entry for Circumstances Code “C6604”
3. Schedule 4, Part 1, omit entry for Circumstances Code “C10126”
4. Schedule 4, Part 1, entry for Circumstances Code “C12871”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
5. Schedule 4, Part 1, entry for Circumstances Code “C12872”
   1. *omit from the column headed “Authority Requirements (part of Circumstances; or Conditions)”:*Compliance with Authority Required procedures *substitute:*Compliance with Written Authority Required procedures
6. Schedule 4, Part 1, omit entry for Circumstances Code “C13166”
7. Schedule 4, Part 1, omit entry for Circumstances Code “C13242”
8. Schedule 4, Part 1, omit entry for Circumstances Code “C13313”
9. Schedule 4, Part 1, omit entry for Circumstances Code “C15108”
10. Schedule 4, Part 1, omit entry for Circumstances Code “C15155”
11. Schedule 4, Part 1, omit entry for Circumstances Code “C15160”
12. Schedule 4, Part 1, omit entry for Circumstances Code “C15162”
13. Schedule 4, Part 1, entry for Circumstances Code “C15177”

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

1. Schedule 4, Part 1, omit entry for Circumstances Code “C15181”
2. Schedule 4, Part 1, entry for Circumstances Code “C15201”

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

1. Schedule 4, Part 1, omit entry for Circumstances Code “C15203”
2. Schedule 4, Part 1, omit entry for Circumstances Code “C15230”
3. Schedule 4, Part 1, omit entry for Circumstances Code “C15239”
4. Schedule 4, Part 1, omit entry for Circumstances Code “C15366”
5. Schedule 4, Part 1, omit entry for Circumstances Code “C15409”
6. Schedule 4, Part 1, after entry for Circumstances Code “C15443”
   1. *insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C15445 | P15445 | CN15445 | Adalimumab | Vision threatening non-infectious uveitis  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug for this condition; AND  The treatment must not exceed 24 weeks under this restriction per authority application.  Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR  Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.  An adequate response to treatment is defined as:  (a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or  (b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or  (c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or  (d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)  The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 15445 |
| C15446 | P15446 | CN15446 | Adalimumab | Vision threatening non-infectious uveitis  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must demonstrated or sustained an adequate response to treatment with this drug for this condition; AND  The treatment must not exceed 24 weeks under this restriction per authority application.  Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR  Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.  An adequate response to treatment is defined as:  (a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or  (b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or  (c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or  (d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)  The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment. | Compliance with Authority Required procedures |
| C15450 | P15450 | CN15450 | Adalimumab | Vision threatening non-infectious uveitis  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 August 2024; AND  Patient must have non-infectious uveitis that is vision threatening with the diagnosis confirmed by an ophthalmologist, rheumatologist, or immunologist; AND  Patient must have failed to achieve an adequate response to corticosteroid therapy in combination with at least 1 immunosuppressive agent prior to commencing non-PBS-subsidised treatment; OR  Patient must have flared when corticosteroid therapy was tapered to a dose of less than or equal to 7.5 mg per day of prednisone or equivalent while on immunomodulatory therapy prior to commencing non-PBS-subsidised treatment; OR  Patient must have failed to achieve an adequate response to prior conventional immunomodulatory therapy in patients for whom corticosteroids are not clinically appropriate prior to commencing non-PBS-subsidised treatment; OR  Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to corticosteroid and immunomodulatory therapy prior to commencing non-PBS-subsidised treatment; AND  Patient must have demonstrated or sustained an adequate response to treatment with this drug for this condition if they have received more than 25 weeks of non-PBS-subsidised treatment; AND  The treatment must not exceed 24 weeks under this restriction.  Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR  Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.  Vision threatening disease is defined as at least 1 of the following:  (a) A decrease in visual acuity of at least 10 letters using an ETDRS chart or equivalent;  (b) A 2-step increase in anterior chamber cells or vitreous haze;  (c) New retinal vasculitis;  (d) New retinal or choroidal lesions;  (e) Other signs of disease progression including visual field changes or electroretinogram changes  An adequate response to treatment is defined as:  (a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or  (b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or  (c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or  (d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only) | Compliance with Authority Required procedures |
| C15454 | P15454 | CN15454 | Cabozantinib | Locally advanced or metastatic differentiated thyroid cancer  Initial treatment  The condition must be refractory to radioactive iodine; OR  Patient must be deemed ineligible for treatment with radioactive iodine; AND  Patient must have progressive disease according to Response Evaluation Criteria in Solid Tumours (RECIST) whilst on treatment with a vascular endothelial growth factor (VEGF)-targeted tyrosine kinase inhibitor (TKI) for this indication; OR  Patient must have developed intolerance of a severity necessitating permanent treatment withdrawal, in the absence of disease progression, to prior VEGF-targeted TKI therapy; AND  Patient must have a WHO performance status of no higher than 2; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have thyroid stimulating hormone adequately suppressed.  Radioactive iodine refractory is defined as:  (i) a lesion without iodine uptake on a radioactive iodine (RAI) scan; or  (ii) having received a cumulative RAI dose of greater than or equal to 600 mCi; or  (iii) progression within 12 months of a single RAI treatment; or  (iv) progression after two RAI treatments administered within 12 months of each other. | Compliance with Authority Required procedures - Streamlined Authority Code 15454 |
| C15455 | P15455 | CN15455 | Atezolizumab | Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC)  1,875 mg administered once every 3 weeks  Patient must be both: (i) initiating treatment, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy; OR  Patient must be continuing existing PBS-subsidised treatment with this drug; OR  Patient must be both: (i) transitioning from existing non-PBS to PBS subsidised supply of this drug, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated.  Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug.  The treatment must be for the purpose of adjuvant therapy following all of: (i) surgical resection, (ii) platinum-based chemotherapy; AND  The condition must have/have had, at treatment commencement, an absence of each of the following gene abnormalities confirmed via tumour material sampling: (i) an activating epidermal growth factor receptor (EGFR) gene mutation, (ii) an anaplastic lymphoma kinase (ALK) gene rearrangement; AND  The condition must have/have had, at treatment commencement, confirmation of programmed cell death ligand 1 (PD-L1) expression on at least 50% of tumour cells; AND  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.  Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred. | Compliance with Authority Required procedures - Streamlined Authority Code 15455 |
| C15456 | P15456 | CN15456 | Midazolam | Generalized convulsive status epilepticus  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition.  At the time of the authority application, practitioners should request the appropriate quantity to cater for the patient's circumstances.  Up to a maximum of 10 syringes for each prescription can be authorised for patients with high frequency seizures. | Compliance with Authority Required procedures |
| C15457 | P15457 | CN15457 | Midazolam | Generalized convulsive status epilepticus  Initial treatment  Patient must have been assessed to be at significant risk of status epilepticus; AND  Patient must have experienced at least one prolonged seizure (greater than 5 minutes duration) requiring emergency medical attention within the previous 5 years.  Patient must be at least one year of age.  The treatment must initiated by a specialist physician experienced in the treatment of epilepsy.  At the time of the authority application, medical practitioners should request the appropriate quantity to cater for the patient's circumstances.  Up to a maximum of 10 syringes for each prescription can be authorised for patients with high frequency seizures. | Compliance with Authority Required procedures |
| C15466 | P15466 | CN15466 | Gilteritinib | Relapsed or refractory Acute Myeloid Leukaemia  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 therapy for this condition; AND  Patient must not have developed disease progression while being treated with this drug for this condition; AND  The treatment must not be for maintenance therapy post-transplant.  Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.  If abnormal blood counts suggest the potential for relapsed AML, following a response to gilteritinib, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.  Progressive disease is defined as the presence of any of the following:  (a) Leukaemic cells in the CSF; or  (b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; or  (c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; or  (d) Extramedullary leukaemia. | Compliance with Authority Required procedures |
| C15467 | P15467 | CN15467 | Larotrectinib | Solid tumours (of certain specified types) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion  Initial treatment  The condition must be confirmed to be positive for a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion prior to treatment initiation with this drug through a pathology report from an Approved Pathology Authority - provide the following evidence: (i) the date of the pathology report substantiating the positive NTRK gene fusion, (ii) the name of the pathology service provider, (iii) the unique identifying number/code linking the pathology test result to the patient; the recency of the pathology report may be of any date; AND  The condition must be non-small cell lung cancer confirmed through a pathology report from an Approved Pathology Authority (of any date); OR  The condition must be soft tissue sarcoma confirmed through a pathology report from an Approved Pathology Authority (of any date); OR  The condition must be confirmed through a pathology report from an Approved Pathology Authority (of any date) as either: (i) glioma, (ii) glioneuronal tumour, (iii) glioblastoma; AND  The condition must be metastatic disease; OR  The condition must be both: (i) locally advanced, (ii) unresectable; OR  The condition must be locally advanced where surgical resection is likely to result in severe morbidity; AND  Patient must have received prior systemic treatment for this disease; OR  Patient must have a condition that predisposes them to an unacceptable risk of intolerance to other systemic therapies; AND  The treatment must be the sole PBS-subsidised anti-cancer therapy for this condition; AND  Patient must not receive more than 3 months of treatment under this restriction.  Patient must not be undergoing treatment through this Initial treatment phase listing where the patient has developed disease progression while receiving this drug for this condition.  Patient must be at least 18 years of age.  The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:  (a) details of the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.  (b) details of the pathology report establishing the carcinoma type (non-small cell lung cancer, soft tissue sarcoma or either glioma/ glioneuronal tumour/ glioblastoma) being treated, if different to the pathology report provided to substantiate the NTRK gene fusion.  (c) details of prior systemic treatment for this disease or details of the condition that predisposes the patient to an unacceptable risk of intolerance to other systemic therapies.  All reports must be documented in the patient's medical records.  If the application is submitted through HPOS form upload or mail, it must include:  (i) details of the proposed prescription; and  (ii) 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). | Compliance with Written Authority Required procedures |
| C15469 | P15469 | CN15469 | Beclometasone with formoterol | Asthma  Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR  Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR  Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.  Patient must be at least 18 years of age. | Compliance with Authority Required procedures - Streamlined Authority Code 15469 |
| C15471 | P15471 | CN15471 | Nivolumab | Resectable non-small cell lung cancer (NSCLC)  The condition must be at least one of: (i) node positive, (ii) at least 4 cm in size; AND  The treatment must be for neoadjuvant use in a patient preparing for surgical resection; AND  Patient must have a WHO performance status of 0 or 1; AND  The treatment must be in combination with platinum-based chemotherapy.  Patient must not be undergoing treatment with more than 3 PBS-subsidised doses of this drug per lifetime for this indication.  In non-squamous type NSCLC where any of the following is known to be present, this drug must not be a PBS benefit: (i) activating epidermal growth factor receptor (EGFR) gene mutation, (ii) anaplastic lymphoma kinase (ALK) gene rearrangement. | Compliance with Authority Required procedures - Streamlined Authority Code 15471 |
| C15473 | P15473 | CN15473 | Adalimumab | Vision threatening non-infectious uveitis  Balance of Supply  Patient must have received PBS-subsidised treatment with this drug for this condition; AND  Patient must have received insufficient therapy with this drug for this condition to complete one of the following: (i) 25 weeks for initial treatment; (ii) 25 weeks for recommencement treatment; (iii) 24 weeks for continuing treatment; (iv) 24 weeks for transitioning from non-PBS to PBS-subsidised treatment. | Compliance with Authority Required procedures |
| C15474 | P15474 | CN15474 | Adalimumab | Vision threatening non-infectious uveitis  Initial treatment  Patient must have non-infectious uveitis that is vision threatening with the diagnosis confirmed by an ophthalmologist, rheumatologist, or immunologist; AND  Patient must have failed to achieve an adequate response to corticosteroid therapy in combination with at least 1 immunosuppressive agent; OR  Patient must have flared when corticosteroid therapy was tapered to a dose of less than or equal to 7.5 mg per day of prednisone or equivalent while on immunomodulatory therapy; OR  Patient must have failed to achieve an adequate response to at least one immunosuppressive agent in patients for whom corticosteroids are not clinically appropriate; OR  Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to corticosteroid and immunomodulatory therapy; AND  The treatment must not exceed 25 weeks under this restriction.  Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR  Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.  Vision threatening disease is defined as at least 1 of the following:  (a) A decrease in visual acuity of at least 10 letters using an ETDRS chart or equivalent;  (b) A 2-step increase in anterior chamber cells or vitreous haze;  (c) New retinal vasculitis;  (d) New retinal or choroidal lesions;  (e) Other signs of disease progression including visual field changes or electroretinogram changes  A failure to achieve an adequate response is defined as failure to meet one or more of the below criteria:  (a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or  (b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or  (c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or  (d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)  Details of prior immunomodulatory agent and corticosteroid treatment, or details of contraindications or developed intolerances necessitating treatment withdrawal, must be documented in the patient's medical record.  The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include details of vision threatening disease.  If the application is submitted through HPOS form upload or mail, it must include:  (i) details of the proposed prescription; and  (ii) 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). | Compliance with Written Authority Required procedures |
| C15477 | P15477 | CN15477 | Selumetinib | Neurofibromatosis type 1  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must be tolerating treatment; AND  Patient must have achieved either: (i) stabilisation of disease, (ii) adequate response to treatment, if have received at least 12 months of treatment with this drug.  Must be treated by a prescriber who is either: (i) a specialist physician with expertise in neurofibromatosis, (ii) a medical practitioner in consultation with a specialist physician with expertise in neurofibromatosis if attendance is not possible due to geographic isolation.  At the time of the authority application, medical practitioners must request the appropriate number of packs of appropriate strength(s) to provide sufficient drug, based on the body surface area (BSA) of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.  Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.  For the purpose of administering this restriction, adequate response is defined as:  1. stability or improvement of the initial baseline measurements prior to initiating treatment with this drug;  2. relevant imaging has not shown an increase in tumour size of 20% or more. | Compliance with Authority Required procedures |
| C15479 | P15479 | CN15479 | Cabozantinib | Locally advanced or metastatic differentiated thyroid cancer  Continuing treatment  The condition must be refractory to radioactive iodine; OR  Patient must be deemed ineligible for treatment with radioactive iodine; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST). | Compliance with Authority Required procedures - Streamlined Authority Code 15479 |
| C15485 | P15485 | CN15485 | Avelumab | Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer  Maintenance therapy - Initial treatment  Patient must have received first-line platinum-based chemotherapy; AND  Patient must not have progressive disease following first-line platinum-based chemotherapy; AND  Patient must have a WHO performance status of 0 or 1; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 15485 |
| C15489 | P15489 | CN15489 | Adalimumab | Vision threatening non-infectious uveitis  Recommencement of treatment  Patient must have a documented history of non-infectious uveitis that is vision threatening; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have demonstrated or sustained an adequate response to treatment prior to having a break in therapy with this drug for this condition; AND  The treatment must not exceed 25 weeks under this restriction.  Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR  Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.  An adequate response to treatment is defined as:  (a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or  (b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or  (c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or  (d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)  The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment. | Compliance with Authority Required procedures |
| C15490 | P15490 | CN15490 | Selumetinib | Neurofibromatosis type 1  Initial treatment  Patient must have plexiform neurofibroma(s) (PN) that is causing/likely to cause at least one of: (i) significant symptoms/morbidity, (ii) disability, (iii) disfigurement, (iv) impairment of normal body function; AND  Patient must have PN for which complete resection cannot be performed; AND  Patient must have either a: (i) Karnofsky, (ii) Lansky Performance Score of at least 70%.  Must be treated by a prescriber who is either: (i) a specialist physician with expertise in neurofibromatosis, (ii) a medical practitioner in consultation with a specialist physician with expertise in neurofibromatosis if attendance is not possible due to geographic isolation.  Patient must be aged between 2 to 18 years; AND  Patient must be able to swallow the whole capsule form of this drug.  At the time of the authority application, medical practitioners must request the appropriate number of packs of appropriate strength(s) to provide sufficient drug, based on the body surface area (BSA) of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.  Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.  For the purpose of administering this restriction, significant symptoms/morbidity are defined as, but not limited to:  1. head and neck PN that can compromise the airway or great vessels;  2. paraspinal PN that can cause myelopathy;  3. brachial or lumbar plexus PN that can cause nerve compression and loss of function;  4. PN that can result in major deformity or significant disfiguring (e.g. orbital PN);  5. PN of the extremity that can cause limb hypertrophy or loss of function; and  6. painful PN.  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). | Compliance with Written Authority Required procedures |
| C15491 | P15491 | CN15491 | Selumetinib | Neurofibromatosis type 1  Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements  Patient must have previously received treatment with this drug for this condition prior to 1 August 2024; OR  Patient must have previously received treatment with another mitogen-activated protein kinase (MEK) inhibitor for this condition prior to 1 August 2024; AND  Patient must have met all other PBS eligibility criteria that a non-'Grandfather' patient would ordinarily be required to meet, meaning that at the time non-PBS-subsidised supply of a MEK inhibitor (including selumetinib) was commenced, the patient: (i) had PN that caused/was likely to cause at least one of: (a) significant symptoms/morbidity, (b) disability, (c) disfigurement, (d) impairment of normal body function; (ii) had PN for which complete PN resection could not be performed either: (a) safely, (b) without causing unacceptable morbidity; (iii) had either a: (a) Karnofsky, (b) Lansky Performance Score of at least 70%; (iv) was aged between 2 to 18 years; (v) was able to swallow the whole capsule form if received non-PBS supply with selumetinib; AND  Patient must be tolerating treatment; AND  Patient must have achieved either: (i) stabilisation of disease, (ii) adequate response to treatment, if have received at least 12 months of treatment.  Must be treated by a prescriber who is either: (i) a specialist physician with expertise in neurofibromatosis, (ii) a medical practitioner in consultation with a specialist physician with expertise in neurofibromatosis if attendance is not possible due to geographic isolation.  At the time of the authority application, medical practitioners must request the appropriate number of packs of appropriate strength(s) to provide sufficient drug, based on the body surface area (BSA) of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.  Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.  For the purpose of administering this restriction, significant symptoms/morbidity are defined as, but not limited to:  1. head and neck PN that can compromise the airway or great vessels;  2. paraspinal PN that can cause myelopathy;  3. brachial or lumbar plexus PN that can cause nerve compression and loss of function;  4. PN that can result in major deformity or significant disfiguring (e.g. orbital PN);  5. PN of the extremity that can cause limb hypertrophy or loss of function; and  6. painful PN.  For the purpose of administering this restriction, adequate response is defined as:  1. stability or improvement of the initial baseline measurements prior to initiating treatment with this drug;  2. relevant imaging has not shown an increase in tumour size of 20% or more.  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). | Compliance with Written Authority Required procedures |
| C15500 | P15500 | CN15500 | Durvalumab | Unresectable Stage III non-small cell lung cancer  Initial treatment  Patient must have received platinum based chemoradiation therapy; AND  The condition must not have progressed following platinum based chemoradiation therapy; AND  Patient must have a WHO performance status of 0 or 1; AND  Patient must be untreated with immunotherapy at commencement of this drug; AND  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 15500 |
| C15509 | P15509 | CN15509 | Larotrectinib | Solid tumours (of certain specified types) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The condition must be either: (i) non-small cell lung cancer, (ii) soft tissue sarcoma, (iii) glioma, (iv), glioneuronal tumour, (v) glioblastoma; AND  The treatment must cease to be a PBS benefit upon radiographic progression; AND  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.  Patient must be at least 18 years of age.  Where radiographic progression is observed, mark any remaining repeat prescriptions with the word 'cancelled'. | Compliance with Authority Required procedures |
| C15510 | P15510 | CN15510 | Lenvatinib | Locally advanced or metastatic differentiated thyroid cancer  Initial treatment  The condition must be refractory to radioactive iodine; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have symptomatic progressive disease prior to treatment; OR  Patient must have progressive disease at critical sites with a high risk of morbidity or mortality where local control cannot be achieved by other measures; AND  Patient must have thyroid stimulating hormone adequately suppressed; AND  Patient must be one in whom surgery is inappropriate; AND  Patient must not be a candidate for radiotherapy with curative intent; AND  Patient must have a WHO performance status of 2 or less.  Radioactive iodine refractory is defined as:  (i) a lesion without iodine uptake on a radioactive iodine (RAI) scan; or  (ii) having received a cumulative RAI dose of greater than or equal to 600 mCi; or  (iii) progression within 12 months of a single RAI treatment; or  (iv) progression after two RAI treatments administered within 12 months of each other. | Compliance with Authority Required procedures - Streamlined Authority Code 15510 |
| C15518 | P15518 | CN15518 | Cabozantinib | Locally advanced or metastatic differentiated thyroid cancer  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 August 2024; AND  The condition must be refractory to radioactive iodine; OR  Patient must be deemed ineligible for treatment with radioactive iodine; AND  Patient must have had progressive disease according to Response Evaluation Criteria in Solid Tumours (RECIST) whilst on treatment with a vascular endothelial growth factor (VEGF)-targeted tyrosine kinase inhibitor (TKI) prior to receiving this drug for this indication; OR  Patient must have developed intolerance of a severity necessitating permanent treatment withdrawal, in the absence of disease progression, to prior VEGF-targeted TKI therapy prior to receiving this drug for this indication; AND  Patient must have had a WHO performance status of no greater than 2 prior to receiving this drug for this indication; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have thyroid stimulating hormone adequately suppressed.  Radioactive iodine refractory is defined as:  (i) a lesion without iodine uptake on a radioactive iodine (RAI) scan; or  (ii) having received a cumulative RAI dose of greater than or equal to 600 mCi; or  (iii) progression within 12 months of a single RAI treatment; or  (iv) progression after two RAI treatments administered within 12 months of each other. | Compliance with Authority Required procedures - Streamlined Authority Code 15518 |
| C15526 | P15526 | CN15526 | Gilteritinib | Relapsed or refractory Acute Myeloid Leukaemia  Initial treatment  The treatment must be the sole PBS-subsidised therapy for this condition; AND  The condition must not be acute promyelocytic leukaemia; AND  The condition must be internal tandem duplication (ITD) and/or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition, confirmed through a pathology report from an Approved Pathology Authority; AND  Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 prior to treatment initiation; AND  The treatment must not be for maintenance therapy post-transplant.  The prescriber must confirm whether the patient has FLT3 ITD or TKD mutation. The test result and date of testing must be provided at the time of application and documented in the patient's file. | Compliance with Authority Required procedures |
| C15527 | P15527 | CN15527 | Nivolumab | Urothelial carcinoma  The treatment must be for each of: (i) adjuvant therapy that is/was initiated within 120 days of radical surgical resection, (ii) muscle invasive type disease, (iii) disease considered to be at high risk of recurrence based on pathologic staging of radical surgery tissue (ypT2-ypT4a or ypN+), but yet to recur, (iv) use as the sole PBS-subsidised anti-cancer treatment for this condition; AND  Patient must have received prior platinum containing neoadjuvant chemotherapy; 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 be undergoing treatment with a dosing regimen as set out in the drug's Therapeutic Goods Administration (TGA) approved Product Information; AND  Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.  An increase in repeat prescriptions, up to a value of 11, may only be sought where the prescribed dosing is 240 mg administered fortnightly. | Compliance with Authority Required procedures |

1. Schedule 4, Part 2, after entry for Variation Code “V15303”
   1. *insert:*

|  |  |  |
| --- | --- | --- |
| V15456 | Midazolam | At the time of the authority application, practitioners should request the appropriate quantity to cater for the patient's circumstances.  Up to a maximum of 10 syringes for each prescription can be authorised for patients with high frequency seizures. |
| V15457 | Midazolam | At the time of the authority application, medical practitioners should request the appropriate quantity to cater for the patient's circumstances.  Up to a maximum of 10 syringes for each prescription can be authorised for patients with high frequency seizures. |

1. Schedule 5, entry for Acamprosate

*omit from the column headed “Brand”:* Acamprosate Mylan

1. Schedule 5, entry for Acarbose in the form Tablet 50 mg
   1. *omit from the column headed “Brand”:* **Acarbose Mylan**
2. Schedule 5, entry for Aciclovir in the form Tablet 800 mg
   1. *insert in the column headed “Brand”, after entry for the Brand “APO-Aciclovir”:* **ARX-ACICLOVIR**
3. Schedule 5, entry for Adalimumab in the form Injection 20 mg in 0.4 mL pre-filled syringe *[GRP-25059]*

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

1. Schedule 5, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[GRP-25060]*

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

1. Schedule 5, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[GRP-25058]*

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

1. Schedule 5, entry for Allopurinol in the form Tablet 100 mg
   1. *insert in the column headed “Brand”, after entry for the Brand “Allosig”:* **APO-ALLOPURINOL**
2. Schedule 5, entry for Amoxicillin with clavulanic acid in the form Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)

*insert in alphabetical order in the column headed “Brand”:* **Alphaclav Duo Viatris**

1. Schedule 5, entry for Bosentan in the form Tablet 125 mg (as monohydrate)
   1. *omit from the column headed “Brand”:* **Bosentan Cipla**
2. Schedule 5, omit entry for Cefazolin
3. Schedule 5, omit entries for Cefepime
4. Schedule 5, omit entries for Ceftriaxone
5. Schedule 5, entry for Cinacalcet in the form Tablet 90 mg (as hydrochloride)
   1. *omit from the column headed “Brand”:* **Cinacalcet Mylan**
6. Schedule 5, entry for Dabigatran etexilate in the form Capsule 75 mg (as mesilate)
   1. *omit from the column headed “Brand”:* **PHARMACOR DABIGATRAN**
7. Schedule 5, entry for Dasatinib in each of the forms: Tablet 100 mg; Tablet 20 mg; Tablet 50 mg; and Tablet 70 mg

*insert in alphabetical order in the column headed “Brand”:* **Dasatinib Viatris**

1. Schedule 5, entry for Ezetimibe
   1. *omit from the column headed “Brand”:* **Blooms The Chemist Ezetimibe**
2. Schedule 5, entry for Ipratropium in the form Nebuliser solution containing ipratropium bromide 250 micrograms (as monohydrate) in 1 mL single dose units, 30
   1. *omit from the column headed “Brand”:* **Aeron 250**
3. Schedule 5, entry for Ipratropium in the form Nebuliser solution containing ipratropium bromide 500 micrograms (as monohydrate) in 1 mL single dose units, 30
   1. *omit from the column headed “Brand”:* **Aeron 500**
4. Schedule 5, entry for Metformin in the form Tablet (extended release) containing metformin hydrochloride 1 g
   1. *omit from the column headed “Brand”:* **Blooms the Chemist Metformin XR 1000**
5. Schedule 5, entry for Metformin in the form Tablet (extended release) containing metformin hydrochloride 500 mg
   1. *omit from the column headed “Brand”:* **Blooms the Chemist Metformin XR 500**
6. Schedule 5, after entry for Methylprednisolone in the form Powder for injection 40 mg (as sodium succinate) with diluent
   1. *insert:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Metoclopramide | GRP-28223 | Injection containing 10 mg metoclopramide hydrochloride (as monohydrate) in 2 mL | Injection | Metoclopramide HCI Medsurge METOCLOPRAMIDE INJECTION BP |

1. Schedule 5, entry for Montelukast in the form Tablet, chewable, 4 mg (as sodium)

*insert in alphabetical order in the column headed “Brand”:* **Montelukast Viatris**

1. Schedule 5, entry for Mycophenolic acid in the form Capsule containing mycophenolate mofetil 250 mg
   1. *omit from the column headed “Brand”:* **CellCept**
2. Schedule 5, entry for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg
   1. *omit from the column headed “Brand”:* **CellCept**
3. Schedule 5, entry for Ondansetron in the form Tablet 4 mg (as hydrochloride dihydrate) *[GRP-19791]*
   1. *substitute:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Ondansetron | GRP-19791 | Tablet 4 mg (as hydrochloride dihydrate) | Oral | APO-Ondansetron APX-Ondansetron Ondansetron-DRLA Ondansetron Mylan Tablets Ondansetron SZ Ondansetron Tablets Viatris Zofran Zotren 4 |

1. Schedule 5, entry for Ondansetron in the form Tablet 8 mg (as hydrochloride dihydrate) *[GRP-19626]*

*substitute:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Ondansetron | GRP-19626 | Tablet 8 mg (as hydrochloride dihydrate) | Oral | APO-Ondansetron APX-Ondansetron Ondansetron-DRLA Ondansetron Mylan Tablets Ondansetron SZ Ondansetron Tablets Viatris Zofran Zotren 8 |

1. Schedule 5, after entry for Oxycodone in the form Tablet containing oxycodone hydrochloride 80 mg (controlled release) *[GRP-19609]*
   1. *insert:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Oxycodone | GRP-23062 | Capsule containing oxycodone hydrochloride 5 mg | Oral | Oxycodone BNM OxyNorm |
| Oxycodone | GRP-23063 | Capsule containing oxycodone hydrochloride 10 mg | Oral | Oxycodone BNM OxyNorm |
| Oxycodone | GRP-23065 | Capsule containing oxycodone hydrochloride 20 mg | Oral | Oxycodone BNM OxyNorm |

1. Schedule 5, entry for Pregabalin in each of the forms: Capsule 25 mg; Capsule 300 mg; and Capsule 75 mg
   1. *omit from the column headed “Brand”:* **Cipla Pregabalin**
2. Schedule 5, entry for Quetiapine in the form Tablet (modified release) 200 mg (as fumarate) *[GRP-20702]*

*substitute:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Quetiapine | GRP-20702 | Tablet (modified release) 200 mg (as fumarate) | Oral | APX-Quetiapine XR QUETIAPINE-AS XR Quetiapine Sandoz XR Quetia XR Seroquel XR Tevatiapine XR |

1. Schedule 5, entry for Quetiapine in the form Tablet (modified release) 300 mg (as fumarate) *[GRP-20713]*

*substitute:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Quetiapine | GRP-20713 | Tablet (modified release) 300 mg (as fumarate) | Oral | APX-Quetiapine XR QUETIAPINE-AS XR Quetiapine Sandoz XR Quetia XR Seroquel XR Tevatiapine XR |

1. Schedule 5, entry for Quetiapine in the form Tablet (modified release) 400 mg (as fumarate) *[GRP-20726]*

*substitute:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Quetiapine | GRP-20726 | Tablet (modified release) 400 mg (as fumarate) | Oral | APX-Quetiapine XR QUETIAPINE-AS XR Quetiapine Sandoz XR Quetia XR Seroquel XR Tevatiapine XR |

1. Schedule 5, entry for Quetiapine in the form Tablet (modified release) 50 mg (as fumarate) *[GRP-20779]*

*substitute:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Quetiapine | GRP-20779 | Tablet (modified release) 50 mg (as fumarate) | Oral | APX-Quetiapine XR QUETIAPINE-AS XR Quetiapine Sandoz XR Quetia XR Seroquel XR Tevatiapine XR |

1. Schedule 5, entry for Ramipril in the form Tablet 10 mg

*insert in alphabetical order in the column headed “Brand”:* **Ramipril Viatris**

1. Schedule 5, entry for Sertraline in each of the forms: Tablet 100 mg (as hydrochloride); and Tablet 50 mg (as hydrochloride)

*insert in alphabetical order in the column headed “Brand”:* **Blooms The Chemist Sertraline**

1. Schedule 5, entry for Tenofovir in the form Tablet containing tenofovir disoproxil fumarate 300 mg

*insert in alphabetical order in the column headed “Brand”:* **TENOFOVIR ARX**

1. Schedule 5, entry for Testosterone
2. *insert in alphabetical order in the column headed “Brand”:* **Gonadron**
3. *insert in alphabetical order in the column headed “Brand”:* **REJUNON 1000**
4. Schedule 5, after entry for Tetrabenazine
   1. *insert:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Timolol | GRP-28880 | Eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL | Application to the eye | Timoptol XE |
| Timolol | GRP-28880 | Eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL (S19A) | Application to the eye | Timoptol XE 0.50% (South Africa) |

1. Schedule 5, entry for Valganciclovir
   1. *omit from the column headed “Brand”:* **VALGANCICLOVIR HETERO**