

**PB 112 of 2023**

**National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023  
(No. 12)**

*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 November 2023

**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 2012   
(PB 71 of 2012). 2

1 Name

1. This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 12)*.
2. This Instrument may also be cited as PB 112 of 2023.

2 Commencement

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

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

Note: This table relates only to the provisions of this instrument as originally made.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

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

3 Authority

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

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

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

1. **Schedule 1, Part 1, entry for Adalimumab**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adalimumab | Injection 20 mg in 0.2 mL pre-filled syringe | Injection |  | Humira | VE | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | C(100) |
|  |  |  |  |  |  | MP | C9715 C11713 C11715 C11716 C11717 C11761 C11767 C11852 C11853 C11854 C11855 C11903 C11966 | P11713 | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C9715 C11713 C11715 C11716 C11717 C11761 C11767 C11852 C11853 C11854 C11855 C11903 C11966 | P9715 P11715 P11716 P11761 P11852 P11854 P11855 | 2 | 3 | 2 |  |  |
|  |  |  |  |  |  | MP | C9715 C11713 C11715 C11716 C11717 C11761 C11767 C11852 C11853 C11854 C11855 C11903 C11966 | P11717 P11767 P11853 P11903 P11966 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C14107 C14136 |  | 2 | 5 | 2 |  | C(100) |
|  | Injection 20 mg in 0.4 mL pre-filled syringe | Injection |  | Amgevita | XT | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 1 |  | C(100) |
|  |  |  |  |  |  | MP | C9715 C11579 C11713 C11715 C11716 C11717 C11718 C11761 C11767 C11852 C11853 C11854 C11855 C11903 C11966 | P11713 | 2 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP | C9715 C11579 C11713 C11715 C11716 C11717 C11718 C11761 C11767 C11852 C11853 C11854 C11855 C11903 C11966 | P9715 P11715 P11716 P11761 P11852 P11854 P11855 | 2 | 3 | 1 |  |  |
|  |  |  |  |  |  | MP | C9715 C11579 C11713 C11715 C11716 C11717 C11718 C11761 C11767 C11852 C11853 C11854 C11855 C11903 C11966 | P11579 P11717 P11718 P11767 P11853 P11903 P11966 | 2 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C14107 C14136 |  | 2 | 5 | 1 |  | C(100) |
|  | Injection 40 mg in 0.4 mL pre-filled pen | Injection |  | Humira | VE | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | C(100) |
|  |  |  |  | Yuflyma | EW | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | C(100) |
|  |  |  |  | Humira | VE | MP | C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730 | P11713 | 2 | 0 | 2 |  |  |
|  |  |  |  | Yuflyma | EW | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11713 | 2 | 0 | 2 |  |  |
|  |  |  |  | Humira | VE | MP | C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 2 | 2 | 2 |  |  |
|  |  |  |  | Yuflyma | EW | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 2 | 2 | 2 |  |  |
|  |  |  |  | Humira | VE | MP | C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730 | P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14498 P14655 P14662 P14670 | 2 | 3 | 2 |  |  |
|  |  |  |  | Yuflyma | EW | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 | 2 | 3 | 2 |  |  |
|  |  |  |  | Humira | VE | MP | C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 | 2 |  |  |
|  |  |  |  | Yuflyma | EW | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 | 2 |  |  |
|  |  |  |  | Humira | VE | MP | C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730 | 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 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C14107 C14136 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  | Yuflyma | EW | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | 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 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C14107 C14136 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  | Humira | VE | MP | C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730 | P12273 | 4 | 2 | 2 |  |  |
|  |  |  |  | Yuflyma | EW | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P12273 | 4 | 2 | 2 |  |  |
|  |  |  |  | Humira | VE | MP | C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730 | P12272 P12315 | 4 | 5 | 2 |  |  |
|  |  |  |  | Yuflyma | EW | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11529 P12272 P12315 | 4 | 5 | 2 |  |  |
|  |  |  |  | Humira | VE | MP | C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336 P13602 P13609 | 6 | 0 | 2 |  |  |
|  |  |  |  | Yuflyma | EW | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336 P13602 P13609 | 6 | 0 | 2 |  |  |
|  | Injection 40 mg in 0.4 mL pre-filled syringe | Injection |  | Humira | VE | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | C(100) |
|  |  |  |  | Yuflyma | EW | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | C(100) |
|  |  |  |  | Humira | VE | MP | C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730 | P11713 | 2 | 0 | 2 |  |  |
|  |  |  |  | Yuflyma | EW | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11713 | 2 | 0 | 2 |  |  |
|  |  |  |  | Humira | VE | MP | C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 2 | 2 | 2 |  |  |
|  |  |  |  | Yuflyma | EW | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 2 | 2 | 2 |  |  |
|  |  |  |  | Humira | VE | MP | C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730 | P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14498 P14655 P14662 P14670 | 2 | 3 | 2 |  |  |
|  |  |  |  | Yuflyma | EW | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 | 2 | 3 | 2 |  |  |
|  |  |  |  | Humira | VE | MP | C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 | 2 |  |  |
|  |  |  |  | Yuflyma | EW | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 | 2 |  |  |
|  |  |  |  | Humira | VE | MP | C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730 | 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 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C14107 C14136 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  | Yuflyma | EW | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | 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 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C14107 C14136 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  | Humira | VE | MP | C9064 C9386 C9715 C11107 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14655 C14656 C14662 C14670 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 6 | 0 | 2 |  |  |
|  |  |  |  | Yuflyma | EW | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 6 | 0 | 2 |  |  |
|  | Injection 40 mg in 0.8 mL pre-filled pen | Injection |  | Amgevita | XT | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | C(100) |
|  |  |  |  | Hadlima | RF | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | C(100) |
|  |  |  |  | Hyrimoz | SZ | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | C(100) |
|  |  |  |  | Idacio | PK | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | C(100) |
|  |  |  |  | Amgevita | XT | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11713 | 2 | 0 | 2 |  |  |
|  |  |  |  | Hadlima | RF | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11713 | 2 | 0 | 2 |  |  |
|  |  |  |  | Hyrimoz | SZ | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11713 | 2 | 0 | 2 |  |  |
|  |  |  |  | Idacio | PK | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11713 | 2 | 0 | 2 |  |  |
|  |  |  |  | Amgevita | XT | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 2 | 2 | 2 |  |  |
|  |  |  |  | Hadlima | RF | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 2 | 2 | 2 |  |  |
|  |  |  |  | Hyrimoz | SZ | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 2 | 2 | 2 |  |  |
|  |  |  |  | Idacio | PK | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 2 | 2 | 2 |  |  |
|  |  |  |  | Amgevita | XT | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 | 2 | 3 | 2 |  |  |
|  |  |  |  | Hadlima | RF | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 | 2 | 3 | 2 |  |  |
|  |  |  |  | Hyrimoz | SZ | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 | 2 | 3 | 2 |  |  |
|  |  |  |  | Idacio | PK | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 | 2 | 3 | 2 |  |  |
|  |  |  |  | Amgevita | XT | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 | 2 |  |  |
|  |  |  |  | Hadlima | RF | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 | 2 |  |  |
|  |  |  |  | Hyrimoz | SZ | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 | 2 |  |  |
|  |  |  |  | Idacio | PK | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 | 2 |  |  |
|  |  |  |  | Amgevita | XT | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | 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 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C14107 C14136 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  | Hadlima | RF | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | 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 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C14107 C14136 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  | Hyrimoz | SZ | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | 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 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C14107 C14136 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  | Idacio | PK | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | 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 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C14107 C14136 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  | Amgevita | XT | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P12273 | 4 | 2 | 2 |  |  |
|  |  |  |  | Hadlima | RF | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P12273 | 4 | 2 | 2 |  |  |
|  |  |  |  | Hyrimoz | SZ | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P12273 | 4 | 2 | 2 |  |  |
|  |  |  |  | Idacio | PK | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P12273 | 4 | 2 | 2 |  |  |
|  |  |  |  | Amgevita | XT | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11529 P12272 P12315 | 4 | 5 | 2 |  |  |
|  |  |  |  | Hadlima | RF | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11529 P12272 P12315 | 4 | 5 | 2 |  |  |
|  |  |  |  | Hyrimoz | SZ | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11529 P12272 P12315 | 4 | 5 | 2 |  |  |
|  |  |  |  | Idacio | PK | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11529 P12272 P12315 | 4 | 5 | 2 |  |  |
|  |  |  |  | Amgevita | XT | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336 P13602 P13609 | 6 | 0 | 2 |  |  |
|  |  |  |  | Hadlima | RF | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336 P13602 P13609 | 6 | 0 | 2 |  |  |
|  |  |  |  | Hyrimoz | SZ | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336 P13602 P13609 | 6 | 0 | 2 |  |  |
|  |  |  |  | Idacio | PK | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11529 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C12272 C12273 C12275 C12315 C12336 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P12275 P12336 P13602 P13609 | 6 | 0 | 2 |  |  |
|  | Injection 40 mg in 0.8 mL pre-filled syringe | Injection |  | Amgevita | XT | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | C(100) |
|  |  |  |  | Hadlima | RF | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | C(100) |
|  |  |  |  | Hyrimoz | SZ | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | C(100) |
|  |  |  |  | Idacio | PK | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | C(100) |
|  |  |  |  | Amgevita | XT | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11713 | 2 | 0 | 2 |  |  |
|  |  |  |  | Hadlima | RF | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11713 | 2 | 0 | 2 |  |  |
|  |  |  |  | Hyrimoz | SZ | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11713 | 2 | 0 | 2 |  |  |
|  |  |  |  | Idacio | PK | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11713 | 2 | 0 | 2 |  |  |
|  |  |  |  | Amgevita | XT | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 2 | 2 | 2 |  |  |
|  |  |  |  | Hadlima | RF | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 2 | 2 | 2 |  |  |
|  |  |  |  | Hyrimoz | SZ | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 2 | 2 | 2 |  |  |
|  |  |  |  | Idacio | PK | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 2 | 2 | 2 |  |  |
|  |  |  |  | Amgevita | XT | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 | 2 | 3 | 2 |  |  |
|  |  |  |  | Hadlima | RF | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 | 2 | 3 | 2 |  |  |
|  |  |  |  | Hyrimoz | SZ | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 | 2 | 3 | 2 |  |  |
|  |  |  |  | Idacio | PK | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 | 2 | 3 | 2 |  |  |
|  |  |  |  | Amgevita | XT | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 | 2 |  |  |
|  |  |  |  | Hadlima | RF | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 | 2 |  |  |
|  |  |  |  | Hyrimoz | SZ | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 | 2 |  |  |
|  |  |  |  | Idacio | PK | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 | 2 |  |  |
|  |  |  |  | Amgevita | XT | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | 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 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C14107 C14136 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  | Hadlima | RF | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | 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 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C14107 C14136 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  | Hyrimoz | SZ | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | 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 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C14107 C14136 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  | Idacio | PK | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | 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 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C14107 C14136 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  | Amgevita | XT | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 6 | 0 | 2 |  |  |
|  |  |  |  | Hadlima | RF | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 6 | 0 | 2 |  |  |
|  |  |  |  | Hyrimoz | SZ | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 6 | 0 | 2 |  |  |
|  |  |  |  | Idacio | PK | MP | C9064 C9386 C9715 C11107 C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11709 C11711 C11713 C11715 C11716 C11717 C11718 C11759 C11761 C11767 C11852 C11853 C11854 C11855 C11861 C11865 C11867 C11903 C11906 C11966 C12098 C12101 C12122 C12123 C12147 C12148 C12155 C12156 C12157 C12158 C12174 C12189 C12190 C12194 C12212 C12214 C12228 C12240 C13556 C13599 C13602 C13609 C13612 C13650 C13681 C13694 C14377 C14378 C14483 C14486 C14488 C14493 C14496 C14498 C14499 C14507 C14567 C14568 C14590 C14655 C14656 C14662 C14670 C14672 C14673 C14683 C14701 C14713 C14730 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 6 | 0 | 2 |  |  |
|  | Injection 80 mg in 0.8 mL pre-filled pen | Injection |  | Humira | VE | MP | C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12155 C12212 C12229 C12273 C12275 C12278 C12306 C14398 C14399 | P12103 P12105 P12155 P12212 P14398 P14399 | 1 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP | C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12155 C12212 C12229 C12273 C12275 C12278 C12306 C14398 C14399 | P12273 | 2 | 2 | 1 |  |  |
|  |  |  |  |  |  | MP | C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12155 C12212 C12229 C12273 C12275 C12278 C12306 C14398 C14399 | P12306 | 2 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12155 C12212 C12229 C12273 C12275 C12278 C12306 C14398 C14399 | P11715 P11716 P11759 P11761 P11762 P11763 P11852 P11854 P11855 P12152 P12229 P12275 P12278 | 3 | 0 | 1 |  |  |
|  | Injection 80 mg in 0.8 mL pre-filled syringe | Injection |  | Humira | VE | MP | C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12155 C12212 C12229 C12273 C12275 C12278 C12306 C14398 C14399 | P12103 P12105 P12155 P12212 P14398 P14399 | 1 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP | C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12155 C12212 C12229 C12273 C12275 C12278 C12306 C14398 C14399 | P12273 | 2 | 2 | 1 |  |  |
|  |  |  |  |  |  | MP | C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12155 C12212 C12229 C12273 C12275 C12278 C12306 C14398 C14399 | P12306 | 2 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C11715 C11716 C11759 C11761 C11762 C11763 C11852 C11854 C11855 C12103 C12105 C12152 C12155 C12212 C12229 C12273 C12275 C12278 C12306 C14398 C14399 | P11715 P11716 P11759 P11761 P11762 P11763 P11852 P11854 P11855 P12152 P12229 P12275 P12278 | 3 | 0 | 1 |  |  |

1. **Schedule 1, Part 1, after entry for Adefovir in the form Tablet containing adefovir dipivoxil 10 mg**

*insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing adefovir dipivoxil 10 mg (S19A) | Oral |  | Adefovir Dipivoxil Tablets 10 mg (SigmaPharm Laboratories) | XW | MP NP | C4490 C4510 |  | 60 | 5 | 30 |  | D(100) |

1. **Schedule 1, Part 1, entry for Alendronic acid with colecalciferol in the form Tablet 70 mg (as alendronate sodium) with 70 micrograms colecalciferol**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Alendronate Plus D3 Sandoz | SZ | MP NP | C6307 C6315 C6320 |  | 4 | 5 | 4 |  |  |

1. *omit from the column headed “Schedule Equivalent” for the brand “Fosamax Plus”:* **a**
2. **Schedule 1, Part 1, entry for Alendronic acid with colecalciferol in the form Tablet 70 mg (as alendronate sodium) with 140 micrograms colecalciferol**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Alendronate Plus D3 Sandoz | SZ | MP NP | C6306 C6319 C6325 |  | 4 | 5 | 4 |  |  |

1. *omit from the column headed “Schedule Equivalent” for the brand “Fosamax Plus 70 mg/140 mcg”:* **a**
2. **Schedule 1, Part 1, entry for Amisulpride in the form Tablet 400 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Amisulpride 400 Winthrop | WA | MP NP | C4246 |  | 60 | 5 | 60 |  |  |

1. **Schedule 1, Part 1, entry for Amitriptyline in the form Tablet containing amitriptyline hydrochloride 25 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Amitriptyline Alphapharm 25 | MQ | MP NP |  |  | 50 | 2 | 50 |  |  |

1. **Schedule 1, Part 1, entry for Amoxicillin in the form Capsule 500 mg (as trihydrate) *[Maximum Quantity: 20; Number of Repeats: 0]***

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Blooms The Chemist Amoxicillin | BG | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |

1. **Schedule 1, Part 1, entry for c in the form Capsule 500 mg (as trihydrate) *[Maximum Quantity: 40; Number of Repeats: 0]***

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Blooms The Chemist Amoxicillin | BG | MP NP |  | P10402 | 40  CN10402 | 0  CN10402 | 20 |  |  |

1. **Schedule 1, Part 1, entry for Amoxicillin in the form Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL**

*insert in the column headed “Schedule Equivalent” (all instances):***a**

1. **Schedule 1, Part 1, entry for Amoxicillin**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL (s19A) | Oral |  | Amoxicillin 250mg/ 5 ml Oral Suspension Sugar Free BP (Kent) | RQ | PDP |  |  | 1 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP NP |  |  | 1 | 0 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Amoxicillin with clavulanic acid in the form Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *[Maximum Quantity: 10; Number of Repeats: 0]***

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125 | BG | MP NP | C5832 C5893 C10413 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |

1. **Schedule 1, Part 1, entry for Amoxicillin with clavulanic acid in the form Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *[Maximum Quantity: 20; Number of Repeats: 0]***

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125 | BG | MP NP | C5832 C5893 C10413 | P10413 | 20 | 0 | 10 |  |  |

1. **Schedule 1, Part 1, entry for Bimekizumab in the form Injection 160 mg in 1 mL single use pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 2]***
2. *omit from the column headed “Circumstances”:* **C14438**
3. *insert in numerical order in the column headed “Circumstances”:* **C14726**
4. *omit from the column headed “Purposes”:* **P14438**
5. *insert in numerical order in the column headed “Purposes”:* **P14726**
6. **Schedule 1, Part 1, entry for Bimekizumab in the form Injection 160 mg in 1 mL single use pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 4]***
7. *omit from the column headed “Circumstances”:* **C14438**
8. *insert in numerical order in the column headed “Circumstances”:* **C14726**
9. **Schedule 1, Part 1, entry for Buprenorphine in the form Transdermal patch 5 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Transdermal patch 5 mg | Transdermal | a | B-Patch | IU | MP NP | C10748 C10752 C10755 C11753 | P10748 P10752 P10755 | 2 | 0 | 2 |  |  |
|  |  |  | a | Bupredermal | TX | MP NP | C10748 C10752 C10755 C11753 | P10748 P10752 P10755 | 2 | 0 | 2 |  |  |
|  |  |  | a | Buprenorphine Sandoz | SZ | MP NP | C10748 C10752 C10755 C11753 | P10748 P10752 P10755 | 2 | 0 | 2 |  |  |
|  |  |  | a | Norspan | MF | MP NP | C10748 C10752 C10755 C11753 | P10748 P10752 P10755 | 2 | 0 | 2 |  |  |
|  |  |  | a | B-Patch | IU | MP NP | C10748 C10752 C10755 C11753 | P11753 | 4 | 0 | 2 |  |  |
|  |  |  | a | Bupredermal | TX | MP NP | C10748 C10752 C10755 C11753 | P11753 | 4 | 0 | 2 |  |  |
|  |  |  | a | Buprenorphine Sandoz | SZ | MP NP | C10748 C10752 C10755 C11753 | P11753 | 4 | 0 | 2 |  |  |
|  |  |  | a | Norspan | MF | MP NP | C10748 C10752 C10755 C11753 | P11753 | 4 | 0 | 2 |  |  |

1. **Schedule 1, Part 1, entry for Buprenorphine in the form Transdermal patch 10 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Transdermal patch 10 mg | Transdermal | a | B-Patch | IU | MP NP | C10748 C10752 C10755 C11753 | P10748 P10752 P10755 | 2 | 0 | 2 |  |  |
|  |  |  | a | Bupredermal | TX | MP NP | C10748 C10752 C10755 C11753 | P10748 P10752 P10755 | 2 | 0 | 2 |  |  |
|  |  |  | a | Buprenorphine Sandoz | SZ | MP NP | C10748 C10752 C10755 C11753 | P10748 P10752 P10755 | 2 | 0 | 2 |  |  |
|  |  |  | a | Norspan | MF | MP NP | C10748 C10752 C10755 C11753 | P10748 P10752 P10755 | 2 | 0 | 2 |  |  |
|  |  |  | a | B-Patch | IU | MP NP | C10748 C10752 C10755 C11753 | P11753 | 4 | 0 | 2 |  |  |
|  |  |  | a | Bupredermal | TX | MP NP | C10748 C10752 C10755 C11753 | P11753 | 4 | 0 | 2 |  |  |
|  |  |  | a | Buprenorphine Sandoz | SZ | MP NP | C10748 C10752 C10755 C11753 | P11753 | 4 | 0 | 2 |  |  |
|  |  |  | a | Norspan | MF | MP NP | C10748 C10752 C10755 C11753 | P11753 | 4 | 0 | 2 |  |  |

1. **Schedule 1, Part 1, entry for Buprenorphine in the form Transdermal patch 15 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Transdermal patch 15 mg | Transdermal | a | B-Patch | IU | MP NP | C10748 C10752 C10755 C11753 | P10748 P10752 P10755 | 2 | 0 | 2 |  |  |
|  |  |  | a | Bupredermal | TX | MP NP | C10748 C10752 C10755 C11753 | P10748 P10752 P10755 | 2 | 0 | 2 |  |  |
|  |  |  | a | Buprenorphine Sandoz | SZ | MP NP | C10748 C10752 C10755 C11753 | P10748 P10752 P10755 | 2 | 0 | 2 |  |  |
|  |  |  | a | Norspan | MF | MP NP | C10748 C10752 C10755 C11753 | P10748 P10752 P10755 | 2 | 0 | 2 |  |  |
|  |  |  | a | B-Patch | IU | MP NP | C10748 C10752 C10755 C11753 | P11753 | 4 | 0 | 2 |  |  |
|  |  |  | a | Bupredermal | TX | MP NP | C10748 C10752 C10755 C11753 | P11753 | 4 | 0 | 2 |  |  |
|  |  |  | a | Buprenorphine Sandoz | SZ | MP NP | C10748 C10752 C10755 C11753 | P11753 | 4 | 0 | 2 |  |  |
|  |  |  | a | Norspan | MF | MP NP | C10748 C10752 C10755 C11753 | P11753 | 4 | 0 | 2 |  |  |

1. **Schedule 1, Part 1, entry for Buprenorphine in the form Transdermal patch 20 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Transdermal patch 20 mg | Transdermal | a | B-Patch | IU | MP NP | C10748 C10752 C10755 C11753 | P10748 P10752 P10755 | 2 | 0 | 2 |  |  |
|  |  |  | a | Bupredermal | TX | MP NP | C10748 C10752 C10755 C11753 | P10748 P10752 P10755 | 2 | 0 | 2 |  |  |
|  |  |  | a | Buprenorphine Sandoz | SZ | MP NP | C10748 C10752 C10755 C11753 | P10748 P10752 P10755 | 2 | 0 | 2 |  |  |
|  |  |  | a | Norspan | MF | MP NP | C10748 C10752 C10755 C11753 | P10748 P10752 P10755 | 2 | 0 | 2 |  |  |
|  |  |  | a | B-Patch | IU | MP NP | C10748 C10752 C10755 C11753 | P11753 | 4 | 0 | 2 |  |  |
|  |  |  | a | Bupredermal | TX | MP NP | C10748 C10752 C10755 C11753 | P11753 | 4 | 0 | 2 |  |  |
|  |  |  | a | Buprenorphine Sandoz | SZ | MP NP | C10748 C10752 C10755 C11753 | P11753 | 4 | 0 | 2 |  |  |
|  |  |  | a | Norspan | MF | MP NP | C10748 C10752 C10755 C11753 | P11753 | 4 | 0 | 2 |  |  |

1. **Schedule 1, Part 1, entry for Carboplatin**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | DBL Carboplatin | PF | MP |  |  | See Note 3 | See Note 3 | 1 |  | D(100) |

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

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Cefepime-AFT | AE | MP NP | C5842 |  | 10 | 0 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Certolizumab pegol**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Certolizumab pegol | Injection 200 mg in 1 mL single use pre-filled syringe | Injection |  | Cimzia | UC | MP | C9063 C9073 C9074 C9105 C9183 C9185 C9431 C9625 C10431 C10459 C10513 C11386 C12392 C14191 C14493 C14499 C14507 C14542 C14571 C14591 C14622 C14659 C14686 C14692 C14714 | P10459 P12392 | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C9063 C9073 C9074 C9105 C9183 C9185 C9431 C9625 C10431 C10459 C10513 C11386 C12392 C14191 C14493 C14499 C14507 C14542 C14571 C14591 C14622 C14659 C14686 C14692 C14714 | P9185 P9625 P14542 | 2 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C9063 C9073 C9074 C9105 C9183 C9185 C9431 C9625 C10431 C10459 C10513 C11386 C12392 C14191 C14493 C14499 C14507 C14542 C14571 C14591 C14622 C14659 C14686 C14692 C14714 | P9063 P9105 P9431 P10431 P14493 P14499 P14507 P14692 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C9063 C9073 C9074 C9105 C9183 C9185 C9431 C9625 C10431 C10459 C10513 C11386 C12392 C14191 C14493 C14499 C14507 C14542 C14571 C14591 C14622 C14659 C14686 C14692 C14714 | P9073 P9074 P9183 P10513 P11386 P14191 P14571 P14591 P14622 P14659 P14686 P14714 | 6 | 0 | 2 |  |  |
|  | Solution for injection 200 mg in 1 mL pre-filled pen | Injection |  | Cimzia | UC | MP | C9063 C9073 C9074 C9105 C9183 C9185 C9431 C9625 C10431 C10459 C10513 C11386 C12392 C14191 C14493 C14499 C14507 C14542 C14571 C14591 C14622 C14659 C14686 C14692 C14714 | P10459 P12392 | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C9063 C9073 C9074 C9105 C9183 C9185 C9431 C9625 C10431 C10459 C10513 C11386 C12392 C14191 C14493 C14499 C14507 C14542 C14571 C14591 C14622 C14659 C14686 C14692 C14714 | P9185 P9625 P14542 | 2 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C9063 C9073 C9074 C9105 C9183 C9185 C9431 C9625 C10431 C10459 C10513 C11386 C12392 C14191 C14493 C14499 C14507 C14542 C14571 C14591 C14622 C14659 C14686 C14692 C14714 | P9063 P9105 P9431 P10431 P14493 P14499 P14507 P14692 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C9063 C9073 C9074 C9105 C9183 C9185 C9431 C9625 C10431 C10459 C10513 C11386 C12392 C14191 C14493 C14499 C14507 C14542 C14571 C14591 C14622 C14659 C14686 C14692 C14714 | P9073 P9074 P9183 P10513 P11386 P14191 P14571 P14591 P14622 P14659 P14686 P14714 | 6 | 0 | 2 |  |  |

1. **Schedule 1, Part 1, entry for Clopidogrel in the form Tablet 75 mg (as hydrogen sulfate) *[Maximum Quantity: 28; Number of Repeats: 5]***

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Blooms Clopidogrel | BG | MP NP |  |  | 28 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Clopidogrel in the form Tablet 75 mg (as hydrogen sulfate) *[Maximum Quantity: 56; Number of Repeats: 5]***

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Blooms Clopidogrel | BG | MP NP |  | P14238 | 56 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Colestyramine**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Sachet containing 4 g oral powder (s19A) | Oral |  | JAMP-Cholestyramine | DZ | MP NP |  |  | 100 | 5 | 30 |  |  |
|  |  |  |  |  |  | MP |  | P6429 | 100 | 11 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Cyclophosphamide in each of the forms: Powder for injection 500 mg (anhydrous); and Powder for injection 1 g (anhydrous)**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | CYCLOPHOSPHAMIDE-REACH | RQ | MP |  |  | See Note 3 | See Note 3 | 1 |  | PB(100) |

1. **Schedule 1, Part 1, entry for Dabigatran etexilate**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dabigatran etexilate | Capsule 75 mg (as mesilate) | Oral | a | PHARMACOR DABIGATRAN | CR | MP NP | C4369 C4381 C4402 | P4381 | 20 | 0 | 10 |  |  |
|  |  |  | a | Pradaxa | BY | MP NP | C4369 C4381 C4402 | P4381 | 20 | 0 | 10 |  |  |
|  |  |  | a | PHARMACOR DABIGATRAN | CR | MP NP | C4369 C4381 C4402 | P4369 | 20 | 1 | 10 |  |  |
|  |  |  | a | Pradaxa | BY | MP NP | C4369 C4381 C4402 | P4369 | 20 | 1 | 10 |  |  |
|  |  |  | a | PHARMACOR DABIGATRAN | CR | MP NP | C4369 C4381 C4402 | P4402 | 60 | 0 | 60 |  |  |
|  |  |  | a | Pradaxa | BY | MP NP | C4369 C4381 C4402 | P4402 | 60 | 0 | 60 |  |  |
|  | Capsule 110 mg (as mesilate) | Oral | a | PHARMACOR DABIGATRAN | CR | MP NP | C4269 C4369 C4381 C4402 C14308 | P4381 | 20 | 0 | 10 |  |  |
|  |  |  | a | Pradaxa | BY | MP NP | C4269 C4369 C4381 C4402 C14308 | P4381 | 20 | 0 | 10 |  |  |
|  |  |  | a | PHARMACOR DABIGATRAN | CR | MP NP | C4269 C4369 C4381 C4402 C14308 | P4369 | 20 | 1 | 10 |  |  |
|  |  |  | a | Pradaxa | BY | MP NP | C4269 C4369 C4381 C4402 C14308 | P4369 | 20 | 1 | 10 |  |  |
|  |  |  | a | Dabigatran Sandoz | SZ | MP NP | C4269 C4402 C14308 | P4402 | 60 | 0 | 60 |  |  |
|  |  |  | a | PHARMACOR DABIGATRAN | CR | MP NP | C4269 C4369 C4381 C4402 C14308 | P4402 | 60 | 0 | 60 |  |  |
|  |  |  | a | Pradaxa | BY | MP NP | C4269 C4369 C4381 C4402 C14308 | P4402 | 60 | 0 | 60 |  |  |
|  |  |  | a | Dabigatran Sandoz | SZ | MP NP | C4269 C4402 C14308 | P4269 | 60 | 5 | 60 |  |  |
|  |  |  | a | PHARMACOR DABIGATRAN | CR | MP NP | C4269 C4369 C4381 C4402 C14308 | P4269 | 60 | 5 | 60 |  |  |
|  |  |  | a | Pradaxa | BY | MP NP | C4269 C4369 C4381 C4402 C14308 | P4269 | 60 | 5 | 60 |  |  |
|  |  |  | a | Dabigatran Sandoz | SZ | MP NP | C4269 C4402 C14308 | P14308 | 120 | 5 | 60 |  |  |
|  |  |  | a | PHARMACOR DABIGATRAN | CR | MP NP | C4269 C4369 C4381 C4402 C14308 | P14308 | 120 | 5 | 60 |  |  |
|  |  |  | a | Pradaxa | BY | MP NP | C4269 C4369 C4381 C4402 C14308 | P14308 | 120 | 5 | 60 |  |  |
|  | Capsule 150 mg (as mesilate) | Oral | a | Dabigatran Sandoz | SZ | MP NP | C4269 C14308 | P4269 | 60 | 5 | 60 |  |  |
|  |  |  | a | PHARMACOR DABIGATRAN | CR | MP NP | C4269 C14308 | P4269 | 60 | 5 | 60 |  |  |
|  |  |  | a | Pradaxa | BY | MP NP | C4269 C14308 | P4269 | 60 | 5 | 60 |  |  |
|  |  |  | a | Dabigatran Sandoz | SZ | MP NP | C4269 C14308 | P14308 | 120 | 5 | 60 |  |  |
|  |  |  | a | PHARMACOR DABIGATRAN | CR | MP NP | C4269 C14308 | P14308 | 120 | 5 | 60 |  |  |
|  |  |  | a | Pradaxa | BY | MP NP | C4269 C14308 | P14308 | 120 | 5 | 60 |  |  |

1. **Schedule 1, Part 1, entry for Darolutamide**

*insert in numerical order in the column headed “Circumstances”:* **C14034**

1. **Schedule 1, Part 1, entry for Durvalumab in each of the forms: Solution concentrate for I.V. infusion 120 mg in 2.4 mL; and Solution concentrate for I.V. infusion 500 mg in 10 mL**

*omit from the column headed “Circumstances”:* **C10126** **C12271** *substitute:* **C10126 C10206 C10509 C12271 C14708**

1. **Schedule 1, Part 1, entry for Entecavir in the form Tablet 1 mg (as monohydrate)**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | ENTAC | LR | MP NP | C5037 C5044 |  | 60 | 5 | 30 |  | D(100) |

1. **Schedule 1, Part 1, entry for Essential amino acids formula with vitamins and minerals**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Essential amino acids formula with vitamins and minerals | Sachets containing oral powder 12.5 g, 30 (EAA Supplement) | Oral |  | EAA Supplement | VF | MP NP | C4925 C4958 |  | 6 | 5 | 1 |  |  |

1. **Schedule 1, Part 1, omit entry for Estradiol with dydrogesterone**
2. **Schedule 1, Part 1, entry for Etanercept**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Etanercept | Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL | Injection |  | Enbrel | PF | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 1 |  | C(100) |
|  |  |  |  |  |  | MP | C7289 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9473 C11107 C12164 C12261 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703 C14713 C14715 | P14508 P14509 | 2 | 1 | 1 |  |  |
|  |  |  |  |  |  | MP | C7289 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9473 C11107 C12164 C12261 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703 C14713 C14715 | P9064 P9386 P9388 P9473 P11107 P12164 P12261 P13532 P13533 P13538 P13593 P13598 P13646 P13647 P14382 P14427 P14483 P14486 P14488 P14498 P14513 P14552 P14553 P14554 P14576 P14577 P14600 P14655 P14662 P14670 P14703 | 2 | 3 | 1 |  |  |
|  |  |  |  |  |  | MP | C7289 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9473 C11107 C12164 C12261 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703 C14713 C14715 | P7289 P8839 P8842 P8873 P8879 P9081 P9123 P9140 P9162 P9377 P9380 P14493 P14499 P14507 P14656 P14713 P14715 | 2 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C14154 C14155 |  | 2 | 5 | 1 |  | C(100) |
|  | Injection 50 mg in 1 mL single use auto-injector, 4 | Injection |  | Enbrel | PF | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 1 |  | C(100) |
|  |  |  |  |  |  | MP | C7289 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9473 C11107 C12164 C12261 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703 C14713 C14715 | P14508 P14509 | 1 | 1 | 1 |  |  |
|  |  |  |  | Brenzys | RF | MP | C7289 C8839 C8842 C8873 C8879 C8887 C8955 C9064 C9081 C9123 C9140 C9156 C9162 C11107 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14581 C14582 C14603 C14629 C14655 C14656 C14662 C14670 C14671 C14673 C14683 C14701 C14703 C14713 C14715 | P9064 P11107 P13532 P13533 P13538 P13593 P13598 P13646 P13647 P14382 P14427 P14483 P14486 P14488 P14498 P14581 P14582 P14603 P14655 P14662 P14670 P14671 P14673 P14703 | 1 | 3 | 1 |  |  |
|  |  |  |  | Enbrel | PF | MP | C7289 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9473 C11107 C12164 C12261 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703 C14713 C14715 | P9064 P9386 P9388 P9473 P11107 P12164 P12261 P13532 P13533 P13538 P13593 P13598 P13646 P13647 P14382 P14427 P14483 P14486 P14488 P14498 P14513 P14552 P14553 P14554 P14576 P14577 P14600 P14655 P14662 P14670 P14703 | 1 | 3 | 1 |  |  |
|  |  |  |  | Brenzys | RF | MP | C7289 C8839 C8842 C8873 C8879 C8887 C8955 C9064 C9081 C9123 C9140 C9156 C9162 C11107 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14581 C14582 C14603 C14629 C14655 C14656 C14662 C14670 C14671 C14673 C14683 C14701 C14703 C14713 C14715 | P7289 P8839 P8842 P8873 P8879 P8887 P8955 P9081 P9123 P9140 P9156 P9162 P14493 P14499 P14507 P14629 P14656 P14683 P14701 P14713 P14715 | 1 | 5 | 1 |  |  |
|  |  |  |  | Enbrel | PF | MP | C7289 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9473 C11107 C12164 C12261 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703 C14713 C14715 | P7289 P8839 P8842 P8873 P8879 P9081 P9123 P9140 P9162 P9377 P9380 P14493 P14499 P14507 P14656 P14713 P14715 | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C14154 C14155 |  | 1 | 5 | 1 |  | C(100) |
|  | Injections 50 mg in 1 mL single use pre-filled syringes, 4 | Injection |  | Enbrel | PF | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 1 |  | C(100) |
|  |  |  |  |  |  | MP | C7289 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9473 C11107 C12164 C12261 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703 C14713 C14715 | P14508 P14509 | 1 | 1 | 1 |  |  |
|  |  |  |  | Brenzys | RF | MP | C7289 C8839 C8842 C8873 C8879 C8887 C8955 C9064 C9081 C9123 C9140 C9156 C9162 C11107 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14581 C14582 C14603 C14629 C14655 C14656 C14662 C14670 C14671 C14673 C14683 C14701 C14703 C14713 C14715 | P9064 P11107 P13532 P13533 P13538 P13593 P13598 P13646 P13647 P14382 P14427 P14483 P14486 P14488 P14498 P14581 P14582 P14603 P14655 P14662 P14670 P14671 P14673 P14703 | 1 | 3 | 1 |  |  |
|  |  |  |  | Enbrel | PF | MP | C7289 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9473 C11107 C12164 C12261 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703 C14713 C14715 | P9064 P9386 P9388 P9473 P11107 P12164 P12261 P13532 P13533 P13538 P13593 P13598 P13646 P13647 P14382 P14427 P14483 P14486 P14488 P14498 P14513 P14552 P14553 P14554 P14576 P14577 P14600 P14655 P14662 P14670 P14703 | 1 | 3 | 1 |  |  |
|  |  |  |  | Brenzys | RF | MP | C7289 C8839 C8842 C8873 C8879 C8887 C8955 C9064 C9081 C9123 C9140 C9156 C9162 C11107 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14581 C14582 C14603 C14629 C14655 C14656 C14662 C14670 C14671 C14673 C14683 C14701 C14703 C14713 C14715 | P7289 P8839 P8842 P8873 P8879 P8887 P8955 P9081 P9123 P9140 P9156 P9162 P14493 P14499 P14507 P14629 P14656 P14683 P14701 P14713 P14715 | 1 | 5 | 1 |  |  |
|  |  |  |  | Enbrel | PF | MP | C7289 C8839 C8842 C8873 C8879 C9064 C9081 C9123 C9140 C9162 C9377 C9380 C9386 C9388 C9473 C11107 C12164 C12261 C13532 C13533 C13538 C13593 C13598 C13646 C13647 C14382 C14427 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14508 C14509 C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14655 C14656 C14662 C14670 C14703 C14713 C14715 | P7289 P8839 P8842 P8873 P8879 P9081 P9123 P9140 P9162 P9377 P9380 P14493 P14499 P14507 P14656 P14713 P14715 | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C14154 C14155 |  | 1 | 5 | 1 |  | C(100) |

1. **Schedule 1, Part 1, entry for Fentanyl in the form Lozenge 600 micrograms (as citrate)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Lozenge 600 micrograms (as citrate) | Buccal |  | Actiq | TB | MP NP | C5904 |  | 60 | 0 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Fentanyl in the form Lozenge 800 micrograms (as citrate)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Lozenge 800 micrograms (as citrate) | Buccal |  | Actiq | TB | MP NP | C5904 |  | 60 | 0 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Fentanyl**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Lozenge 1200 micrograms (as citrate) | Buccal |  | Actiq | TB | MP NP | C5904 C5915 | P5915 | 9 | 0 | 9 |  |  |
|  |  |  |  |  |  | MP NP | C5904 C5915 | P5904 | 60 | 0 | 30 |  |  |
|  | Lozenge 1600 micrograms (as citrate) | Buccal |  | Actiq | TB | MP NP | C5904 C5915 | P5915 | 9 | 0 | 9 |  |  |
|  |  |  |  |  |  | MP NP | C5904 C5915 | P5904 | 60 | 0 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Fentanyl in the form Tablet (orally disintegrating) 400 micrograms (as citrate)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet (orally disintegrating) 400 micrograms (as citrate) | Buccal |  | Fentora | TB | MP NP | C6027 |  | 56 | 0 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Fentanyl in the form Tablet (orally disintegrating) 600 micrograms (as citrate)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet (orally disintegrating) 600 micrograms (as citrate) | Buccal |  | Fentora | TB | MP NP | C6027 |  | 56 | 0 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Fentanyl in the form Tablet (orally disintegrating) 800 micrograms (as citrate)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet (orally disintegrating) 800 micrograms (as citrate) | Buccal |  | Fentora | TB | MP NP | C6027 |  | 56 | 0 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Filgrastim in the form Injection 300 micrograms in 0.5 mL single-use pre-filled syringe**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Neupogen | AN | MP | C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696 |  | 20 | 11 | 10 |  | D(100) |

1. **Schedule 1, Part 1, entry for Filgrastim**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Injection 300 micrograms in 1 mL | Injection |  | Neupogen | AN | MP | C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696 |  | 20 | 11 | 10 |  | D(100) |

1. **Schedule 1, Part 1, entry for Filgrastim in the form Injection 480 micrograms in 0.5 mL single-use pre-filled syringe**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Neupogen | AN | MP | C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696 |  | 20 | 11 | 10 |  | D(100) |

1. **Schedule 1, Part 1, entry for Filgrastim**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Injection 480 micrograms in 1.6 mL | Injection |  | Neupogen | AN | MP | C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696 |  | 20 | 11 | 10 |  | D(100) |

1. **Schedule 1, Part 1, entry for Fluorouracil in the form Injection 2500 mg in 50 mL**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | DBL Fluorouracil Injection BP | PF | MP | C6266 C6297 |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. **Schedule 1, Part 1, entry for Golimumab**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Golimumab | Injection 50 mg in 0.5 mL single use pre-filled pen | Injection |  | Simponi | JC | MP | C9063 C9064 C9069 C9105 C9153 C9155 C9429 C9431 C10434 C10436 C10461 C10515 C11431 C14190 C14488 C14507 C14519 C14556 C14557 C14604 C14626 C14655 C14662 C14670 C14692 | P9064 P9069 P9153 P9155 P9429 P10436 P10515 P11431 P14190 P14488 P14556 P14557 P14626 P14655 P14662 P14670 | 1 | 3 | 1 |  |  |
|  |  |  |  |  |  | MP | C9063 C9064 C9069 C9105 C9153 C9155 C9429 C9431 C10434 C10436 C10461 C10515 C11431 C14190 C14488 C14507 C14519 C14556 C14557 C14604 C14626 C14655 C14662 C14670 C14692 | P9063 P9105 P9431 P10434 P10461 P14507 P14519 P14604 P14692 | 1 | 5 | 1 |  |  |
|  | Injection 50 mg in 0.5 mL single use pre-filled syringe | Injection |  | Simponi | JC | MP | C9063 C9064 C9069 C9105 C9153 C9155 C9429 C9431 C10434 C10436 C10461 C10515 C11431 C14190 C14488 C14507 C14519 C14556 C14557 C14604 C14626 C14655 C14662 C14670 C14692 | P9064 P9069 P9153 P9155 P9429 P10436 P10515 P11431 P14190 P14488 P14556 P14557 P14626 P14655 P14662 P14670 | 1 | 3 | 1 |  |  |
|  |  |  |  |  |  | MP | C9063 C9064 C9069 C9105 C9153 C9155 C9429 C9431 C10434 C10436 C10461 C10515 C11431 C14190 C14488 C14507 C14519 C14556 C14557 C14604 C14626 C14655 C14662 C14670 C14692 | P9063 P9105 P9431 P10434 P10461 P14507 P14519 P14604 P14692 | 1 | 5 | 1 |  |  |
|  | Injection 100 mg in 1 mL single use pre-filled pen | Injection |  | Simponi | JC | MP | C9651 C9705 C9745 C9770 C9822 C9823 | P9745 | 1 | 1 | 1 |  |  |
|  |  |  |  |  |  | MP | C9651 C9705 C9745 C9770 C9822 C9823 | P9651 P9770 | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C9651 C9705 C9745 C9770 C9822 C9823 | P9705 P9822 P9823 | 3 | 0 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Ibandronic acid**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Concentrated injection for I.V. infusion 6 mg (as ibandronate sodium monohydrate) in 6 mL | Injection |  | Bondronat | IX | MP | C5291 C9333 |  | 1 | 11 | 1 |  | PB(100) |

1. **Schedule 1, Part 1, entry for Imatinib in the form Capsule 100 mg (as mesilate)**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | CIPLA IMATINIB ADULT | LR | MP | C9203 C9204 C9206 C9207 C9209 C9240 C9243 C9274 C9276 C9296 C12525 C12527 C12536 C12541 C12542 C12543 | P9203 P9207 P12525 P12527 P12542 P12543 | 60 | 2 | 60 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | CIPLA IMATINIB ADULT | LR | MP | C9203 C9204 C9206 C9207 C9209 C9240 C9243 C9274 C9276 C9296 C12525 C12527 C12536 C12541 C12542 C12543 | P9204 P9206 P9209 P9240 P9243 P9274 P9276 P9296 P12536 P12541 | 60 | 5 | 60 |  |  |

1. **Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate)**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | CIPLA IMATINIB ADULT | LR | MP | C9203 C9204 C9206 C9207 C9209 C9240 C9243 C9274 C9276 C9296 C12525 C12527 C12536 C12541 C12542 C12543 | P9203 P9207 P12525 P12527 P12542 P12543 | 30 | 2 | 30 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | CIPLA IMATINIB ADULT | LR | MP | C9203 C9204 C9206 C9207 C9209 C9240 C9243 C9274 C9276 C9296 C12525 C12527 C12536 C12541 C12542 C12543 | P9204 P9206 P9209 P9240 P9243 P9274 P9276 P9296 P12536 P12541 | 30 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Infliximab**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infliximab | Powder for I.V. infusion 100 mg | Injection |  | Inflectra | PF | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 1 |  | PB(100) |
|  |  |  |  | Remicade | JC | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 1 |  | PB(100) |
|  |  |  |  | Renflexis | OQ | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 1 |  | PB(100) |
|  |  |  |  | Inflectra | PF | MP | C14504 C14505 C14585 C14638 C14683 C14689 C14701 C14723 | P14504 P14505 P14585 P14638 | 3 | 2 | 1 |  | PB(100) |
|  |  |  |  | Remicade | JC | MP | C14504 C14505 |  | 3 | 2 | 1 |  | PB(100) |
|  |  |  |  | Renflexis | OQ | MP | C14504 C14505 C14585 C14638 C14683 C14689 C14701 C14723 | P14504 P14505 P14585 P14638 | 3 | 2 | 1 |  | PB(100) |
|  |  |  |  | Inflectra | PF | MP | C14504 C14505 C14585 C14638 C14683 C14689 C14701 C14723 | P14683 P14689 P14701 P14723 | 5 | 3 | 1 |  | PB(100) |
|  |  |  |  | Renflexis | OQ | MP | C14504 C14505 C14585 C14638 C14683 C14689 C14701 C14723 | P14683 P14689 P14701 P14723 | 5 | 3 | 1 |  | PB(100) |
|  | Solution for injection 120 mg in 1 mL pre-filled pen | Injection |  | Remsima SC | EW | MP | C11826 C11910 C13039 C13040 C13043 C13045 C13056 C13058 C13061 C13068 C13069 C13077 C13078 C13079 C13080 C13094 C13096 C13097 C13104 C14515 C14668 | P13104 | 1 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP | C11826 C11910 C13039 C13040 C13043 C13045 C13056 C13058 C13061 C13068 C13069 C13077 C13078 C13079 C13080 C13094 C13096 C13097 C13104 C14515 C14668 | P13040 P13058 P13061 P13068 P13094 P13096 | 2 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP | C11826 C11910 C13039 C13040 C13043 C13045 C13056 C13058 C13061 C13068 C13069 C13077 C13078 C13079 C13080 C13094 C13096 C13097 C13104 C14515 C14668 | P13039 P13045 P13069 P13077 P13078 P13080 P13097 | 2 | 2 | 1 |  |  |
|  |  |  |  |  |  | MP | C11826 C11910 C13039 C13040 C13043 C13045 C13056 C13058 C13061 C13068 C13069 C13077 C13078 C13079 C13080 C13094 C13096 C13097 C13104 C14515 C14668 | P11826 P11910 P13043 P13056 P13079 P14515 P14668 | 2 | 5 | 1 |  |  |
|  | Solution for injection 120 mg in 1 mL pre-filled syringe | Injection |  | Remsima SC | EW | MP | C11826 C11910 C13039 C13040 C13043 C13045 C13056 C13058 C13061 C13068 C13069 C13077 C13078 C13079 C13080 C13094 C13096 C13097 C13104 C14515 C14668 | P13104 | 1 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP | C11826 C11910 C13039 C13040 C13043 C13045 C13056 C13058 C13061 C13068 C13069 C13077 C13078 C13079 C13080 C13094 C13096 C13097 C13104 C14515 C14668 | P13040 P13058 P13061 P13068 P13094 P13096 | 2 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP | C11826 C11910 C13039 C13040 C13043 C13045 C13056 C13058 C13061 C13068 C13069 C13077 C13078 C13079 C13080 C13094 C13096 C13097 C13104 C14515 C14668 | P13039 P13045 P13069 P13077 P13078 P13080 P13097 | 2 | 2 | 1 |  |  |
|  |  |  |  |  |  | MP | C11826 C11910 C13039 C13040 C13043 C13045 C13056 C13058 C13061 C13068 C13069 C13077 C13078 C13079 C13080 C13094 C13096 C13097 C13104 C14515 C14668 | P11826 P11910 P13043 P13056 P13079 P14515 P14668 | 2 | 5 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Insulin neutral with insulin isophane**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Injections (human), cartridges, 50 units-50 units per mL, 3 mL, 5 | Injection |  | Mixtard 50/50 Penfill 3 mL | NO | MP NP |  |  | 5 | 1 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Ixekizumab**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ixekizumab | Injection 80 mg in 1 mL single dose pre-filled pen | Injection |  | Taltz | LY | MP | C6696 C8830 C8892 C9172 C9429 C9431 C11089 C11096 C11107 C11138 C11154 C11834 C11918 C11958 C11959 C11981 C14453 C14461 C14655 C14662 C14670 C14692 | P9429 P14655 P14662 P14670 | 2 | 1 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8830 C8892 C9172 C9429 C9431 C11089 C11096 C11107 C11138 C11154 C11834 C11918 C11958 C11959 C11981 C14453 C14461 C14655 C14662 C14670 C14692 | P6696 P8830 P8892 P9172 P9431 P11834 P11918 P11958 P11959 P11981 P14692 | 2 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8830 C8892 C9172 C9429 C9431 C11089 C11096 C11107 C11138 C11154 C11834 C11918 C11958 C11959 C11981 C14453 C14461 C14655 C14662 C14670 C14692 | P11089 P11096 P11107 P11138 P11154 P14453 P14461 | 2 | 3 | 2 |  |  |

1. **Schedule 1, Part 1, entry for Macrogol 3350**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Macrogol 3350 | Powder for oral solution 510 g | Oral |  | OsmoLax | KY | MP | See Note 2 | See Note 2 | See Note 2 | See Note 2 | 1 |  | C(100) |
|  |  |  |  |  |  | MP NP | C4171 C4173 C4177 C4179 C4180 C6170 | P4171 P4173 P4177 P4179 P4180 | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP NP | C4171 C4173 C4177 C4179 C4180 C6170 | P6170 | 2 | 3 | 1 |  |  |
|  | Sachets containing powder for oral solution 13.125 g with electrolytes, 30 | Oral | a | APOHEALTH Macrogol with Electrolytes | GX | MP | See Note 2 | See Note 2 | See Note 2 | See Note 2 | 1 |  | C(100) |
|  |  |  | a | APO-MACROGOL plus ELECTROLYTES | TX | MP | See Note 2 | See Note 2 | See Note 2 | See Note 2 | 1 |  | C(100) |
|  |  |  | a | Chemists' Own Macrogol with Electrolytes | RW | MP | See Note 2 | See Note 2 | See Note 2 | See Note 2 | 1 |  | C(100) |
|  |  |  | a | Macrovic | RF | MP | See Note 2 | See Note 2 | See Note 2 | See Note 2 | 1 |  | C(100) |
|  |  |  | a | Molaxole | GO | MP | See Note 2 | See Note 2 | See Note 2 | See Note 2 | 1 |  | C(100) |
|  |  |  | a | Movicol | NE | MP | See Note 2 | See Note 2 | See Note 2 | See Note 2 | 1 |  | C(100) |
|  |  |  | a | APOHEALTH Macrogol with Electrolytes | GX | MP NP | C4576 C4577 C4580 C4596 C4601 C6171 | P4576 P4577 P4580 P4596 P4601 | 1 | 5 | 1 |  |  |
|  |  |  | a | APO-MACROGOL plus ELECTROLYTES | TX | MP NP | C4576 C4577 C4580 C4596 C4601 C6171 | P4576 P4577 P4580 P4596 P4601 | 1 | 5 | 1 |  |  |
|  |  |  | a | Chemists' Own Macrogol with Electrolytes | RW | MP NP | C4576 C4577 C4580 C4596 C4601 C6171 | P4576 P4577 P4580 P4596 P4601 | 1 | 5 | 1 |  |  |
|  |  |  | a | Macrovic | RF | MP NP | C4576 C4577 C4580 C4596 C4601 C6171 | P4576 P4577 P4580 P4596 P4601 | 1 | 5 | 1 |  |  |
|  |  |  | a | Molaxole | GO | MP NP | C4576 C4577 C4580 C4596 C4601 C6171 | P4576 P4577 P4580 P4596 P4601 | 1 | 5 | 1 |  |  |
|  |  |  | a | Movicol | NE | MP NP | C4576 C4577 C4580 C4596 C4601 C6171 | P4576 P4577 P4580 P4596 P4601 | 1 | 5 | 1 |  |  |
|  |  |  | a | APOHEALTH Macrogol with Electrolytes | GX | MP NP | C4576 C4577 C4580 C4596 C4601 C6171 | P6171 | 2 | 3 | 1 |  |  |
|  |  |  | a | APO-MACROGOL plus ELECTROLYTES | TX | MP NP | C4576 C4577 C4580 C4596 C4601 C6171 | P6171 | 2 | 3 | 1 |  |  |
|  |  |  | a | Chemists' Own Macrogol with Electrolytes | RW | MP NP | C4576 C4577 C4580 C4596 C4601 C6171 | P6171 | 2 | 3 | 1 |  |  |
|  |  |  | a | Macrovic | RF | MP NP | C4576 C4577 C4580 C4596 C4601 C6171 | P6171 | 2 | 3 | 1 |  |  |
|  |  |  | a | Molaxole | GO | MP NP | C4576 C4577 C4580 C4596 C4601 C6171 | P6171 | 2 | 3 | 1 |  |  |
|  |  |  | a | Movicol | NE | MP NP | C4576 C4577 C4580 C4596 C4601 C6171 | P6171 | 2 | 3 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Meloxicam in the form Tablet 7.5 mg**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Meloxicam Viatris | AL | MP NP | C4907 C4962 |  | 30 | 3 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Metformin in the form Tablet containing metformin hydrochloride 500 mg**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Blooms The Chemist Metformin 500 mg | BG | MP NP |  |  | 100 | 5 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Metformin in the form Tablet containing metformin hydrochloride 850 mg**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Blooms The Chemist Metformin 850 mg | BG | MP NP |  |  | 60 | 5 | 60 |  |  |

1. **Schedule 1, Part 1, entry for Metformin in the form Tablet containing metformin hydrochloride 1 g**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Blooms The Chemist Metformin 1000 mg | BG | MP NP |  |  | 90 | 5 | 90 |  |  |

1. **Schedule 1, Part 1, after entry for Morphine in the form Oral solution containing morphine hydrochloride trihydrate 2 mg per mL, 1 mL**

*insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Oral solution containing morphine sulfate 2 mg per mL in 100 mL bottle, 1 mL (S19A) | Oral |  | Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) | DZ | MP NP | C10764 C10770 C10777 C11697 | P10764 P10770 P10777 | 200 | 0 | 100 |  |  |
|  |  |  |  |  |  | PDP | C10859 |  | 200 | 0 | 100 |  |  |
|  |  |  |  |  |  | MP NP | C10764 C10770 C10777 C11697 | P11697 | 1000 | 1 | 100 |  |  |
|  | Oral solution containing morphine sulfate 2 mg per mL in 500 mL bottle, 1 mL (S19A) | Oral |  | Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) | DZ | MP NP | C10764 C10770 C10777 C11697 | P10764 P10770 P10777 | 200 | 0 | 500 |  |  |
|  |  |  |  |  |  | PDP | C10859 |  | 200 | 0 | 500 |  |  |
|  |  |  |  |  |  | MP NP | C10764 C10770 C10777 C11697 | P11697 | 2000 | 1 | 500 |  |  |

1. **Schedule 1, Part 1, after entry for Morphine in the form Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL**

*insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Oral solution containing morphine sulfate 10 mg per 5 mL in 100 mL bottle, 1 mL (S19A) | Oral |  | Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL | LM | MP NP | C10764 C10770 C10777 C11697 | P10764 P10770 P10777 | 200 | 0 | 100 |  |  |
|  |  |  |  |  |  | PDP | C10859 |  | 200 | 0 | 100 |  |  |
|  |  |  |  |  |  | MP NP | C10764 C10770 C10777 C11697 | P11697 | 1000 | 1 | 100 |  |  |
|  | Oral solution containing morphine sulfate 10 mg per 5 mL in 300 mL bottle, 1 mL (S19A) | Oral |  | Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL | LM | MP NP | C10764 C10770 C10777 C11697 | P10764 P10770 P10777 | 200 | 0 | 300 |  |  |
|  |  |  |  |  |  | PDP | C10859 |  | 200 | 0 | 300 |  |  |
|  |  |  |  |  |  | MP NP | C10764 C10770 C10777 C11697 | P11697 | 2100 | 1 | 300 |  |  |

1. **Schedule 1, Part 1, entry for Moxonidine in the form Tablet 400 micrograms**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Moxonidine MYL | AF | MP NP | C4944 C14289 | P4944 | 30 | 5 | 30 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Moxonidine MYL | AF | MP NP | C4944 C14289 | P14289 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid | Oral | a | MYCOTEX | CR | MP |  |  | 120 | 5 | 120 |  |  |
|  |  |  | a | Myfortic | NV | MP |  |  | 120 | 5 | 120 |  |  |
|  |  |  | a | MYCOTEX | CR | MP |  | P4084 P4095 P9692 P9809 | 240 CN4084 CN4095 CN9692 CN9809 | 5 CN4084 CN4095 CN9692 CN9809 | 120 |  | C(100) |
|  |  |  | a | Myfortic | NV | MP |  | P4084 P4095 P9692 P9809 | 240 CN4084 CN4095 CN9692 CN9809 | 5 CN4084 CN4095 CN9692 CN9809 | 120 |  | C(100) |

1. **Schedule 1, Part 1, entry for Nevirapine in the form Tablet 200 mg**
2. *insert in the column headed “Schedule Equivalent” for the brand “Nevirapine Alphapharm”:* **a**
3. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Nevirapine Viatris | AL | MP NP | C4454 C4512 |  | 120 | 5 | 60 |  | D(100) |

1. **Schedule 1, Part 1, entry for Nicorandil in each of the forms: Tablets 10 mg, 60; and Tablets 20 mg, 60**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Ikorel | SW | MP NP |  |  | 1 | 5 | 1 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Ikorel | SW | MP NP |  | P14238 | 2 | 5 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Nivolumab in each of the forms: Injection concentrate for I.V. infusion 40 mg in 4 mL; and Injection concentrate for I.V. infusion 100 mg in 10 mL**
2. *omit from the column headed “Circumstances”:* **C13888**
3. *insert in numerical order in the column headed “Circumstances”:* **C14676**
4. **Schedule 1, Part 1, entry for Octreotide in the form Injection 500 micrograms (as acetate) in 1 mL**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Octreotide MaxRx | GQ | MP | C6369 C6390 C8165 C9232 C9233 C9289 |  | 90 | 11 | 5 |  | D(100) |

1. **Schedule 1, Part 1, entry for Olanzapine in the form Tablet 5 mg (orally disintegrating)**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Zypine ODT | AF | MP NP | C5856 C5869 |  | 28 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Olanzapine in each of the forms: Tablet 10 mg (orally disintegrating); Tablet 15 mg (orally disintegrating); and Tablet 20 mg (orally disintegrating)**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Zypine ODT | AF | MP NP | C5856 C5869 |  | 28 | 5 | 28 |  |  |

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

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Zypine ODT | AF | MP NP | C5856 C5869 |  | 28 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Olmesartan in the form Tablet containing olmesartan medoxomil 20 mg *[Maximum Quantity: 30; Number of Repeats: 5]***

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Blooms The Chemist Olmesartan | BG | MP NP |  |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Olmesartan in the form Tablet containing olmesartan medoxomil 20 mg *[Maximum Quantity: 60; Number of Repeats: 5]***

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Blooms The Chemist Olmesartan | BG | MP NP |  | P14238 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Olmesartan in the form Tablet containing olmesartan medoxomil 40 mg *[Maximum Quantity: 30; Number of Repeats: 5]***

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Blooms The Chemist Olmesartan | BG | MP NP |  |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Olmesartan in the form Tablet containing olmesartan medoxomil 40 mg *[Maximum Quantity: 60; Number of Repeats: 5]***

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Blooms The Chemist Olmesartan | BG | MP NP |  | P14238 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Olmesartan with amlodipine**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Olmesartan with amlodipine | Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate) | Oral | a | OLMEKAR | RW | MP NP | C4373 C14257 | P4373 | 30 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine 20/5 APOTEX | TX | MP NP | C4373 C14257 | P4373 | 30 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine - MYL 20/5 | AF | MP NP | C4373 C14257 | P4373 | 30 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine Sandoz | SZ | MP NP | C4373 C14257 | P4373 | 30 | 5 | 30 |  |  |
|  |  |  | a | Pharmacor Olmesartan Amlodipine 20/5 | CR | MP NP | C4373 C14257 | P4373 | 30 | 5 | 30 |  |  |
|  |  |  | a | Sevikar 20/5 | AL | MP NP | C4373 C14257 | P4373 | 30 | 5 | 30 |  |  |
|  |  |  | a | OLMEKAR | RW | MP NP | C4373 C14257 | P14257 | 60 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine 20/5 APOTEX | TX | MP NP | C4373 C14257 | P14257 | 60 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine - MYL 20/5 | AF | MP NP | C4373 C14257 | P14257 | 60 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine Sandoz | SZ | MP NP | C4373 C14257 | P14257 | 60 | 5 | 30 |  |  |
|  |  |  | a | Pharmacor Olmesartan Amlodipine 20/5 | CR | MP NP | C4373 C14257 | P14257 | 60 | 5 | 30 |  |  |
|  |  |  | a | Sevikar 20/5 | AL | MP NP | C4373 C14257 | P14257 | 60 | 5 | 30 |  |  |
|  | Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) | Oral | a | OLMEKAR | RW | MP NP | C4373 |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine 40/5 APOTEX | TX | MP NP | C4373 |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine - MYL 40/5 | AF | MP NP | C4373 |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine Sandoz | SZ | MP NP | C4373 |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Pharmacor Olmesartan Amlodipine 40/5 | CR | MP NP | C4373 |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Sevikar 40/5 | AL | MP NP | C4373 |  | 30 | 5 | 30 |  |  |
|  | Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) | Oral | a | OLMEKAR | RW | MP NP | C4373 |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine 40/10 APOTEX | TX | MP NP | C4373 |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine - MYL 40/10 | AF | MP NP | C4373 |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine Sandoz | SZ | MP NP | C4373 |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Pharmacor Olmesartan Amlodipine 40/10 | CR | MP NP | C4373 |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Sevikar 40/10 | AL | MP NP | C4373 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Ondansetron in the form Wafer 8 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Wafer 8 mg | Oral |  | Zofran Zydis | AS | MP NP | C10498 |  | 10 | 1 | 10 |  |  |

1. **Schedule 1, Part 1, entry for Oxaliplatin in the form Solution concentrate for I.V. infusion 100 mg in 20 mL**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | DBL Oxaliplatin Concentrate | PF | MP |  |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. **Schedule 1, Part 1, omit entry for Pancrelipase**
2. **Schedule 1, Part 1, entry for Pembrolizumab**

*insert in numerical order in the column headed “Circumstances”:* **C14727**

1. **Schedule 1, Part 1, entry for Pemetrexed in each of the forms: Powder for I.V. infusion 100 mg (as disodium); and Powder for I.V. infusion 500 mg (as disodium)**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Pemetrexed-AFT | AE | MP |  |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. **Schedule 1, Part 1, entry for Pirfenidone in the form Tablet 267 mg**
2. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Pirfenidone Ameda | XT | MP | C13378 C13380 C13381 |  | 270 | 5 | 90 |  |  |

1. *insert in the column headed “Schedule Equivalent” for the brand “Pirfenidone Sandoz”:* **a**
2. **Schedule 1, Part 1, entry for Pirfenidone in the form Tablet 801mg**
3. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Pirfenidone Ameda | XT | MP | C13380 |  | 90 | 5 | 90 |  |  |

1. *insert in the column headed “Schedule Equivalent” for the brand “Pirfenidone Sandoz”:* **a**
2. **Schedule 1, Part 1, entry for Pregabalin in each of the forms: Capsule 25 mg; Capsule 75 mg; Capsule 150 mg; and Capsule 300 mg**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | BTC Pregabalin | BG | MP NP | C4172 |  | 56 | 5 | 56 |  |  |

1. **Schedule 1, Part 1, entry for Pyridostigmine**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing pyridostigmine bromide 180 mg (modified release) s19A | Oral |  | Pyridostigmine Bromide Extended-Release Tablets (Rising) | DZ | MP |  |  | 100 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Raltegravir**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 25 mg (as potassium) | Oral |  | Isentress | MK | MP NP | C4274 C4275 |  | 360 | 5 | 60 |  | D(100) |
|  | Tablet 100 mg (as potassium) | Oral |  | Isentress | MK | MP NP | C4274 C4275 |  | 360 | 5 | 60 |  | D(100) |

1. **Schedule 1, Part 1, entry for Ranitidine**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Syrup 150 mg (as hydrochloride) per 10 mL, 300 mL | Oral |  | Zantac Syrup | AS | MP NP |  |  | 2 | 5 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Riociguat**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Riociguat | Tablet 500 micrograms | Oral |  | Adempas | BN | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 42 |  | D(100) |
|  | Tablet 1 mg | Oral |  | Adempas | BN | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 42 |  | D(100) |
|  | Tablet 1.5 mg | Oral |  | Adempas | BN | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 42 |  | D(100) |
|  | Tablet 2 mg | Oral |  | Adempas | BN | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 42 |  | D(100) |
|  | Tablet 2.5 mg | Oral |  | Adempas | BN | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 42 |  | D(100) |

1. **Schedule 1, Part 1, entry for Rosuvastatin in each of the forms: Tablet 5 mg (as calcium); Tablet 10 mg (as calcium); Tablet 20 mg (as calcium); and Tablet 40 mg (as calcium) *[Maximum Quantity: 60; Number of Repeats: 5]***

*omit from the column headed “Authorised Prescriber” for the brand “Blooms Rosuvastatin”:* **MP NP NP**  *substitute:* **MP NP**

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

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Secukinumab | Injection 150 mg in 1 mL pre-filled pen | Injection |  | Cosentyx | NV | MP | C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9429 C9431 C10431 C11089 C11096 C11138 C11154 C11389 C11390 C11502 C12392 C14220 C14430 C14462 C14655 C14662 C14670 C14692 | P11390 P12392 | 1 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP | C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9429 C9431 C10431 C11089 C11096 C11138 C11154 C11389 C11390 C11502 C12392 C14220 C14430 C14462 C14655 C14662 C14670 C14692 | P9064 P9429 | 1 | 2 | 1 |  |  |
|  |  |  |  |  |  | MP | C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9429 C9431 C10431 C11089 C11096 C11138 C11154 C11389 C11390 C11502 C12392 C14220 C14430 C14462 C14655 C14662 C14670 C14692 | P9063 P9105 P9431 P10431 P14692 | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9429 C9431 C10431 C11089 C11096 C11138 C11154 C11389 C11390 C11502 C12392 C14220 C14430 C14462 C14655 C14662 C14670 C14692 | P8831 P9064 | 2 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9429 C9431 C10431 C11089 C11096 C11138 C11154 C11389 C11390 C11502 C12392 C14220 C14430 C14462 C14655 C14662 C14670 C14692 | P6696 P8830 P8892 P9063 P9105 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9429 C9431 C10431 C11089 C11096 C11138 C11154 C11389 C11390 C11502 C12392 C14220 C14430 C14462 C14655 C14662 C14670 C14692 | P9069 P9078 P9155 P14655 P14662 P14670 | 4 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP | C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9429 C9431 C10431 C11089 C11096 C11138 C11154 C11389 C11390 C11502 C12392 C14220 C14430 C14462 C14655 C14662 C14670 C14692 | P11389 P11502 P14220 | 5 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP | C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9429 C9431 C10431 C11089 C11096 C11138 C11154 C11389 C11390 C11502 C12392 C14220 C14430 C14462 C14655 C14662 C14670 C14692 | P9069 P9078 P9155 P11089 P11096 P11138 P11154 P14430 P14462 | 8 | 0 | 2 |  |  |

1. **Schedule 1, Part 1, entry for Sitagliptin with metformin in the form Tablet (modified release) containing 50 mg sitagliptin with 1000 mg metformin hydrochloride**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet (modified release) containing 50 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | a | Janumet XR | XW | MP | C6333 C6334 C6344 C6443 C7507 C7530 |  | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 |  | 56 | 5 | 56 |  |  |
|  |  |  | a | Sitagliptin/Metformin Sandoz XR | SZ | MP | C6333 C6334 C6344 C6443 C7507 C7530 |  | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 |  | 56 | 5 | 56 |  |  |

1. **Schedule 1, Part 1, entry for Sitagliptin with metformin in the form Tablet (modified release) containing 100 mg sitagliptin with 1000 mg metformin hydrochloride**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet (modified release) containing 100 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | a | Janumet XR | XW | MP | C6333 C6334 C6344 C6443 C7507 C7530 |  | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 |  | 28 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin/Metformin Sandoz XR | SZ | MP | C6333 C6334 C6344 C6443 C7507 C7530 |  | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 |  | 28 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, omit entry for Sterculia with frangula bark**
2. **Schedule 1, Part 1, entry for Tobramycin in the form Injection 80 mg in 2 mL**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | DBL Tobramycin | PF | MP NP | C5446 C5490 C5519 |  | 10 | 1 | 5 |  |  |

1. **Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled syringe *[Maximum Quantity: 4; Number of Repeats: 6]***
2. *omit from the column headed “Circumstances”:* **P14195**
3. *insert in numerical order in the column headed “Circumstances”:* **C14195**
4. **Schedule 1, Part 1, entry for Tofacitinib**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Tofacitinib | Oral solution 1 mg per mL, 240 mL | Oral |  | Xeljanz | PF | MP | C9417 C14647 C14649 C14650 C14652 C14697 | P9417 P14649 P14650 P14652 | 1 | 3 | 1 |  |  |
|  |  |  |  |  |  | MP | C9417 C14647 C14649 C14650 C14652 C14697 | P14647 P14697 | 1 | 5 | 1 |  |  |
|  | Tablet 5 mg | Oral |  | Xeljanz | PF | MP | C9064 C9417 C9431 C11883 C11886 C11915 C11940 C11944 C11945 C11956 C11975 C11976 C11978 C12174 C12976 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14647 C14649 C14650 C14652 C14655 C14662 C14670 C14692 C14697 C14720 | P9064 P9417 P11915 P11940 P11944 P11945 P11956 P11975 P11976 P12174 P14483 P14486 P14488 P14498 P14649 P14650 P14652 P14655 P14662 P14670 | 56 | 3 | 56 |  |  |
|  |  |  |  |  |  | MP | C9064 C9417 C9431 C11883 C11886 C11915 C11940 C11944 C11945 C11956 C11975 C11976 C11978 C12174 C12976 C14483 C14486 C14488 C14493 C14498 C14499 C14507 C14647 C14649 C14650 C14652 C14655 C14662 C14670 C14692 C14697 C14720 | P9431 P11883 P11886 P11978 P12976 P14493 P14499 P14507 P14647 P14692 P14697 P14720 | 56 | 5 | 56 |  |  |
|  | Tablet 10 mg | Oral |  | Xeljanz | PF | MP | C11883 C11915 C11940 C11975 C11976 C12976 | P11915 P11940 P11975 P11976 | 56 | 3 | 56 |  |  |
|  |  |  |  |  |  | MP | C11883 C11915 C11940 C11975 C11976 C12976 | P11883 P12976 | 56 | 5 | 56 |  |  |

1. **Schedule 1, Part 1, entry for Upadacitinib**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Upadacitinib | Tablet 15 mg | Oral |  | Rinvoq | VE | MP | C9064 C9431 C10434 C11886 C11944 C11945 C11956 C11978 C12174 C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011 C14198 C14199 C14208 C14213 C14216 C14217 C14483 C14486 C14488 C14498 C14613 C14633 C14655 C14662 C14670 C14692 C14696 C14698 C14709 | P13959 | 28 | 1 | 28 |  |  |
|  |  |  |  |  |  | MP | C9064 C9431 C10434 C11886 C11944 C11945 C11956 C11978 C12174 C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011 C14198 C14199 C14208 C14213 C14216 C14217 C14483 C14486 C14488 C14498 C14613 C14633 C14655 C14662 C14670 C14692 C14696 C14698 C14709 | P9064 P11944 P11945 P11956 P12174 P12504 P14208 P14213 P14216 P14217 P14483 P14486 P14488 P14498 P14655 P14662 P14670 | 28 | 3 | 28 |  |  |
|  |  |  |  |  |  | MP | C9064 C9431 C10434 C11886 C11944 C11945 C11956 C11978 C12174 C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011 C14198 C14199 C14208 C14213 C14216 C14217 C14483 C14486 C14488 C14498 C14613 C14633 C14655 C14662 C14670 C14692 C14696 C14698 C14709 | P12499 P12508 | 28 | 4 | 28 |  |  |
|  |  |  |  |  |  | MP | C9064 C9431 C10434 C11886 C11944 C11945 C11956 C11978 C12174 C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011 C14198 C14199 C14208 C14213 C14216 C14217 C14483 C14486 C14488 C14498 C14613 C14633 C14655 C14662 C14670 C14692 C14696 C14698 C14709 | P9431 P10434 P11886 P11978 P12493 P12494 P13930 P13958 P14011 P14198 P14199 P14613 P14633 P14692 P14696 P14698 P14709 | 28 | 5 | 28 |  |  |
|  | Tablet 30 mg | Oral |  | Rinvoq | VE | MP | C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011 C14696 C14698 C14711 C14728 | P13959 | 28 | 1 | 28 |  |  |
|  |  |  |  |  |  | MP | C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011 C14696 C14698 C14711 C14728 | P14711 | 28 | 2 | 28 |  |  |
|  |  |  |  |  |  | MP | C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011 C14696 C14698 C14711 C14728 | P12504 | 28 | 3 | 28 |  |  |
|  |  |  |  |  |  | MP | C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011 C14696 C14698 C14711 C14728 | P12499 P12508 | 28 | 4 | 28 |  |  |
|  |  |  |  |  |  | MP | C12493 C12494 C12499 C12504 C12508 C13930 C13958 C13959 C14011 C14696 C14698 C14711 C14728 | P12493 P12494 P13930 P13958 P14011 P14696 P14698 P14728 | 28 | 5 | 28 |  |  |
|  | Tablet 45 mg | Oral |  | Rinvoq | VE | MP | C11976 C13990 C13999 C14014 C14653 C14696 C14710 C14721 C14734 | P14653 P14696 P14710 P14721 P14734 | 28 | 2 | 28 |  |  |
|  |  |  |  |  |  | MP | C11976 C13990 C13999 C14014 C14653 C14696 C14710 C14721 C14734 | P11976 P13990 P13999 P14014 | 28 | 3 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Vancomycin in the form Powder for injection 500 mg (500,000 I.U.) (as hydrochloride)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Powder for injection 500 mg (500,000 I.U.) (as hydrochloride) | Injection |  | Vancomycin Alphapharm | AF | MP | C5716 C5717 C5769 | P5717 | 2 | 0 | 1 |  |  |
|  |  |  |  |  |  | PDP | C5801 |  | 2 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP | C5716 C5717 C5769 | P5716 P5769 | 5 | 0 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Vancomycin in the form Powder for injection 1 g (1,000,000 I.U.) (as hydrochloride)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Powder for injection 1 g (1,000,000 I.U.) (as hydrochloride) | Injection |  | Vancomycin Alphapharm | AF | MP | C5716 C5717 C5769 | P5717 | 1 | 0 | 1 |  |  |
|  |  |  |  |  |  | PDP | C5801 |  | 1 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP | C5716 C5717 C5769 | P5716 P5769 | 3 | 0 | 1 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Vfend | PF | MP NP | C4683 C4685 C5692 C5725 C5748 | P4685 | 56 | 0 | 56 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Vfend | PF | MP NP | C4683 C4685 C5692 C5725 C5748 | P4683 P5692 P5725 P5748 | 56 | 2 | 56 |  |  |

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**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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 C14729 C14735 | P14729 P14735 | 1 | 0 | 1 |  | PB(100) |
|  |  |  | a | APO-Zoledronic Acid | TX | MP | C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328 |  | 1 | 11 | 1 |  | PB(100) |
|  |  |  | a | DEZTRON | DZ | MP | C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328 |  | 1 | 11 | 1 |  | PB(100) |
|  |  |  | a | Zoledronate-DRLA 4 | RZ | MP | C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328 |  | 1 | 11 | 1 |  | PB(100) |
|  |  |  | a | Zoledronic Acid Accord | OC | MP | C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328 C14729 C14735 | P5605 P5703 P5704 P5735 P9268 P9304 P9317 P9328 | 1 | 11 | 1 |  | PB(100) |
|  |  |  | a | Zometa | SA | MP | C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328 |  | 1 | 11 | 1 |  | PB(100) |

1. **Schedule 1, Part 2, after entry for Ertugliflozin with sitagliptin in the form Tablet containing 15 mg ertugliflozin with 100 mg sitagliptin**

*insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Essential amino acids formula with vitamins and minerals | Sachets containing oral powder 12.5 g, 50 (EAA Supplement) | Oral |  | EAA Supplement | VF | MP NP | C4925 C4958 |  | 4 | 5 | 1 |  |  |
| Estradiol with dydrogesterone | Tablet 1 mg-5 mg | Oral |  | Femoston-Conti | GO | MP NP |  |  | 28 | 5 | 28 |  |  |
| Filgrastim | Injection 300 micrograms in 1 mL | Injection |  | Neupogen | AN | MP | C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696 |  | 20 | 11 | 10 |  | D(100) |
|  | Injection 480 micrograms in 1.6 mL | Injection |  | Neupogen | AN | MP | C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696 |  | 20 | 11 | 10 |  | D(100) |
| Insulin neutral with insulin isophane | Injections (human), cartridges, 50 units-50 units per mL, 3 mL, 5 | Injection |  | Mixtard 50/50 Penfill 3 mL | NO | MP NP |  |  | 5 | 1 | 1 |  |  |

1. **Schedule 1, Part 2, omit entry for Labetalol**
2. **Schedule 1, Part 2, after entry for Insulin neutral with insulin isophane**

*insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Macrogol 3350 | Oral liquid 13.125 g in 25 mL with electrolytes, 500 mL | Oral |  | Movicol Liquid | NE | MP NP | C4576 C4577 C4580 C4596 C4601 C6171 | P6171 | 2 | 3 | 1 |  |  |
|  |  |  |  |  |  | MP NP | C4576 C4577 C4580 C4596 C4601 C6171 | P4576 P4577 P4580 P4596 P4601 | 2 | 5 | 1 |  |  |
| Pancrelipase | Capsule (containing enteric coated microtablets) providing not less than 25,000 BP units of lipase activity | Oral |  | Panzytrat 25000 | TM | MP NP |  |  | 200 | 10 | 100 |  |  |
|  |  |  |  |  |  | MP |  | P5779 | 200 | 21 | 100 |  |  |
| Raltegravir | Tablet 25 mg (as potassium) | Oral |  | Isentress | MK | MP NP | C4274 C4275 |  | 360 | 5 | 60 |  | D(100) |
|  | Tablet 100 mg (as potassium) | Oral |  | Isentress | MK | MP NP | C4274 C4275 |  | 360 | 5 | 60 |  | D(100) |
| Sterculia with frangula bark | Granules 620 mg-80 mg per g, 500 g | Oral |  | Normacol Plus | NE | MP NP | C5613 C5640 C5685 C5720 C5775 C5776 C5804 C6139 | P5613 P5640 P5685 P5720 P5775 P5776 P5804 | 1 | 1 | 1 |  |  |
|  |  |  |  |  |  | MP NP | C5613 C5640 C5685 C5720 C5775 C5776 C5804 C6139 | P6139 | 1 | 3 | 1 |  |  |

1. **Schedule 3, after details relevant to Responsible Person code IT**

*insert:*

|  |  |  |
| --- | --- | --- |
| IU | AU Pharma Pty Ltd | 84 132 146 313 |

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C11634 | P11634 |  | Ankylosing spondylitis Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 11634 |

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|  | C12131 | P12131 |  | Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 4 weeks old at the time of application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |

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|  | C12175 | P12175 |  | Ankylosing spondylitis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |
|  | C12176 | P12176 |  | Ankylosing spondylitis Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 4 weeks old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |

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|  | C12234 | P12234 |  | Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 4 weeks old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |

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|  | C13606 | P13606 |  | Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a BASDAI score. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |

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|  | C13682 | P13682 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |

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

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|  | C14655 | P14655 |  | Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C14656 | P14656 |  | Ankylosing spondylitis Subsequent continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C14662 | P14662 |  | Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C14670 | P14670 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C14672 | P14672 |  | Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Authority Required procedures |
|  | C14673 | P14673 |  | Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures |
|  | C14683 | P14683 |  | Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 14683 |
|  | C14701 | P14701 |  | Ankylosing spondylitis Subsequent continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 14701 |
|  | C14713 | P14713 |  | Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C14730 | P14730 |  | Ankylosing spondylitis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |

1. **Schedule 4, Part 1, entry for Atorvastatin**

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|  |  | P7598 |  | For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |

1. **Schedule 4, Part 1, entry for Bimekizumab**
2. *omit:*

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|  | C14438 | P14438 |  | Severe chronic plaque psoriasis Grandfathered patient - Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) Patient must have a documented severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where lesions have been present for at least 6 months prior to commencing non-PBS-subsidised treatment with this drug for this condition; AND Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 October 2023; AND Patient must have a documented failure to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments prior to commencing non-PBS-subsidised treatment with this drug for this condition: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND Patient must have a documented Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing non-PBS-subsidised treatment with this drug for this condition; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheets including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and (c) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. The most recent PASI assessment must be no more than 4 weeks old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. | Compliance with Written Authority Required procedures |

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

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|  | C14726 | P14726 |  | Severe chronic plaque psoriasis Grandfathered patient - Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) Patient must have a documented severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where lesions have been present for at least 6 months prior to commencing non-PBS-subsidised treatment with this drug for this condition; AND Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 October 2023; AND Patient must have a documented failure to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments prior to commencing non-PBS-subsidised treatment with this drug for this condition: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND Patient must have had disease, prior to treatment with this drug for this condition, classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling were rated as severe or very severe; or (ii) the skin area affected was 30% or more of the face, palm of a hand or sole of a foot; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheets including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and (c) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. The most recent PASI assessment must be no more than 4 weeks old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. | Compliance with Written Authority Required procedures |

1. **Schedule 4, Part 1, entry for Certolizumab pegol**
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|  | C9430 | P9430 |  | Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |

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|  | C9442 | P9442 |  | Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C9537 | P9537 |  | Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C9610 | P9610 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application. Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |

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

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|  | C14659 | P14659 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C14686 | P14686 |  | Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C14692 | P14692 |  | Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C14714 | P14714 |  | Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |

1. **Schedule 4, Part 1, entry for Darolutamide**

*insert in numerical order after existing text:*

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

1. **Schedule 4, Part 1, entry for Durvalumab**
2. *insert after entry for Circumstances Code “C10126”:*

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|  | C10206 |  |  | Extensive-stage small cell lung cancer Initial treatment The condition must be previously untreated; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be in combination with etoposide and a platinum-based antineoplastic drug. | Compliance with Authority Required procedures - Streamlined Authority Code 10206 |
|  | C10509 |  |  | Extensive-stage small cell lung cancer Continuing treatment - 4 weekly treatment regimen The treatment must be as monotherapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10509 |

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

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|  | C14708 |  |  | Locally advanced, metastatic or recurrent biliary tract cancer (intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer) Patient must have either of the following at treatment initiation: (i) locally advanced biliary tract cancer that is untreated with systemic anti-cancer therapy in the unresectable setting, (ii) metastatic biliary tract cancer that is untreated with systemic anti-cancer therapy in the metastatic setting. 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/have been initiated with both: (i) gemcitabine, (ii) cisplatin (refer to Product Information of gemcitabine and cisplatin for dosing information); AND Patient must not have developed disease progression while being treated with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 14708 |

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

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|  | C9410 | P9410 |  | Ankylosing spondylitis Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C9429 | P9429 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |

1. *omit:*

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|  | C9481 | P9481 |  | Ankylosing spondylitis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be used to determine response for all subsequent continuing treatments. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 9481 |
|  | C9487 | P9487 |  | Ankylosing spondylitis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |
|  | C9502 | P9502 |  | Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C9554 | P9554 |  | Ankylosing spondylitis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |

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|  | C13535 | P13535 |  | Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |

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|  | C13540 | P13540 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application. Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |

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|  | C14655 | P14655 |  | Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C14656 | P14656 |  | Ankylosing spondylitis Subsequent continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C14662 | P14662 |  | Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C14670 | P14670 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C14671 | P14671 |  | Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Authority Required procedures |
|  | C14673 | P14673 |  | Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures |
|  | C14683 | P14683 |  | Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 14683 |
|  | C14701 | P14701 |  | Ankylosing spondylitis Subsequent continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 14701 |
|  | C14703 | P14703 |  | Ankylosing spondylitis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |
|  | C14713 | P14713 |  | Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C14715 | P14715 |  | Ankylosing spondylitis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |

1. **Schedule 4, Part 1, entry for Fenofibrate**

*omit:*

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| --- | --- | --- | --- | --- | --- |
|  |  | P7640 |  | For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |

1. **Schedule 4, Part 1, entry for Fluvastatin**

*omit:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P7598 |  | For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |

1. **Schedule 4, Part 1, entry for Gemfibrozil**

*omit:*

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| --- | --- | --- | --- | --- | --- |
|  |  | P7640 |  | For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |

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

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| --- | --- | --- | --- | --- | --- |
|  | C9414 | P9414 |  | Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C9428 | P9428 |  | Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |

1. *omit:*

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| --- | --- | --- | --- | --- | --- |
|  | C9430 | P9430 |  | Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |

1. *omit:*

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| --- | --- | --- | --- | --- | --- |
|  | C9503 | P9503 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application. Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |

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

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|  | C14655 | P14655 |  | Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C14662 | P14662 |  | Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C14670 | P14670 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C14692 | P14692 |  | Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |

1. **Schedule 4, Part 1, entry for Ibandronic acid**

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|  | C5291 |  |  | Bone metastases The condition must be due to breast cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 5291 |
|  | C9333 |  |  | Bone metastases The condition must be due to breast cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 9333 |

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

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|  | C13095 | P13095 |  | Ankylosing spondylitis Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND The treatment must have both: (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. | Compliance with Written Authority Required procedures |

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|  | C14668 | P14668 |  | Ankylosing spondylitis Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND The treatment must have both: (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. All measurements provided must be no more than 1 month old at the time of application. | Compliance with Written Authority Required procedures |
|  | C14683 | P14683 |  | Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 14683 |
|  | C14689 | P14689 |  | Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 14689 |
|  | C14701 | P14701 |  | Ankylosing spondylitis Subsequent continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 14701 |
|  | C14723 | P14723 |  | Ankylosing spondylitis Subsequent continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 14723 |

1. **Schedule 4, Part 1, entry for Ixekizumab**
2. *omit:*

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|  | C10997 | P10997 |  | Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 4 weeks old at the time of application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C11030 | P11030 |  | Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 4 weeks old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C11054 | P11054 |  | Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a BASDAI score. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C11061 | P11061 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |

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

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|  | C14655 | P14655 |  | Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C14662 | P14662 |  | Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C14670 | P14670 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C14692 | P14692 |  | Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |

1. **Schedule 4, Part 1, entry for Nivolumab**
2. *omit:*

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|  | C13888 |  |  | Advanced or metastatic gastro-oesophageal cancers The condition must be a gastro-oesophageal cancer type as specified in the drug's 'Indications' section of the approved Australian Product Information; AND The treatment must be prescribed in accordance with the drug's 'Indications' section of the approved Australian Production Information with respect to each of: (i) concomitant drugs/therapies, (ii) line of therapy (i.e. prior treatments, if any); AND Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND Patient must be untreated with programmed cell death-1/ligand-1 (PD-1/PD-L1) inhibitor therapy for gastro-oesophageal cancer. Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first: (i) disease progression despite treatment with this drug, (ii) 24 months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs. | Compliance with Authority Required procedures - Streamlined Authority Code 13888 |

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

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|  | C14676 |  |  | Advanced or metastatic gastro-oesophageal cancers Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND Patient must be untreated (up until initiating this drug) with programmed cell death-1/ligand-1 (PD-1/PD-L1) inhibitor therapy for gastro-oesophageal cancer. Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first: (i) disease progression despite treatment with this drug, (ii) 24 months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs. Patient must be in one of the three population subsets described below. Population 1 Conditions: gastric cancer, gastro-oesophageal junction cancer, oesophageal adenocarcinoma Concomitant therapies: chemotherapy containing at least a fluoropyrimidine drug plus a platinum drug Line of treatment: first-line drug treatment Additional clinical finding: HER2 negative Population 2 Condition: oesophageal squamous cell carcinoma (can be recurrent) Concomitant therapies: chemotherapy containing at least a fluoropyrimidine drug plus a platinum drug Line of treatment: first-line drug treatment Additional clinical finding: unresectable Population 3 Condition: oesophageal squamous cell carcinoma (can be recurrent) Line of treatment: second-line drug treatment after chemotherapy containing at least a fluoropyrimidine drug plus a platinum drug Additional clinical finding: unresectable | Compliance with Authority Required procedures - Streamlined Authority Code 14676 |

1. **Schedule 4, Part 1, entry for Pancreatic extract**

*omit:*

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| --- | --- | --- | --- | --- | --- |
|  |  | P5779 |  | Cystic fibrosis Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |

1. **Schedule 4, Part 1, entry for Pembrolizumab**

*insert in numerical order after existing text:*

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| --- | --- | --- | --- | --- | --- |
|  | C14727 |  |  | Stage II or Stage III triple negative breast cancer The treatment must be initiated in combination with neoadjuvant chemotherapy; AND The condition must not have progressed/recurred whilst on treatment with this drug. Patient must not be undergoing treatment with this drug beyond 52 cumulative weeks under this restriction; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 7 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 4 repeat prescriptions. | Compliance with Authority Required procedures - Streamlined Authority Code 14727 |

1. **Schedule 4, Part 1, entry for Pravastatin**

*omit:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P7598 |  | For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |

1. **Schedule 4, Part 1, entry for Rosuvastatin**

*omit:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P7598 |  | For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |

1. **Schedule 4, Part 1, entry for Secukinumab**
2. *omit:*

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| --- | --- | --- | --- | --- | --- |
|  | C9414 | P9414 |  | Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C9428 | P9428 |  | Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |

1. *omit:*

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| --- | --- | --- | --- | --- | --- |
|  | C9430 | P9430 |  | Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |

1. *omit:*

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| --- | --- | --- | --- | --- | --- |
|  | C9503 | P9503 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application. Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |

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

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| --- | --- | --- | --- | --- | --- |
|  | C14655 | P14655 |  | Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C14662 | P14662 |  | Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C14670 | P14670 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C14692 | P14692 |  | Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |

1. **Schedule 4, Part 1, entry for Simvastatin**

*omit:*

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| --- | --- | --- | --- | --- | --- |
|  |  | P7598 |  | For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |

1. **Schedule 4, Part 1, entry for Sulfasalazine**

*omit:*

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| --- | --- | --- | --- | --- | --- |
|  |  | P4894 |  | For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |

1. **Schedule 4, Part 1, entry for Tofacitinib**
2. *insert after entry for Circumstances Code “C9064”:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C9417 | P9417 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |

1. *omit:*

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| --- | --- | --- | --- | --- | --- |
|  | C9429 | P9429 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |

1. *insert after entry for Circumstances Code “C11978”:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C12174 | P12174 |  | Ankylosing spondylitis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |

1. *omit:*

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|  | C14210 | P14210 |  | Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 4 weeks old at the time of application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C14211 | P14211 |  | Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 4 weeks old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C14224 | P14224 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C14225 | P14225 |  | Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a BASDAI score. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C14345 | P14345 |  | Ankylosing spondylitis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2023; AND Patient must have had at least 2 of the following prior to commencing non-PBS-subsidised treatment: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months prior to commencing non-PBS-subsidised treatment; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response to NSAIDs and must have been demonstrated prior to initiation of non-PBS subsidised treatment with this biological medicine for this condition: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must have been determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. If the above requirement to demonstrate an elevated ESR or CRP could not be met, the application must state the reason this criterion could not be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |

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

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|  | C14647 | P14647 |  | Severe active juvenile idiopathic arthritis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 December 2023; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate prior to initiating treatment with this drug for this condition; OR Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens prior to initiating treatment with this drug for this condition: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be under 18 years of age. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: (a) an active joint count of at least 20 active (swollen and tender) joints; OR (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to prior treatment must be documented in the patient's medical records. The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records: (a) the date of assessment of severe active juvenile idiopathic arthritis; and (b) details of prior treatment including dose and duration of treatment. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Authority Required procedures |
|  | C14649 | P14649 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Authority Required procedures |
|  | C14650 | P14650 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Active joints are defined as: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records: (a) the date of assessment of severe active juvenile idiopathic arthritis; and (b) the date of the last continuing prescription. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Authority Required procedures |
|  | C14652 | P14652 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: (a) an active joint count of at least 20 active (swollen and tender) joints; OR (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to prior treatment must be documented in the patient's medical records. The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records: (a) the date of assessment of severe active juvenile idiopathic arthritis; and (b) details of prior treatment including dose and duration of treatment. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Authority Required procedures |
|  | C14655 | P14655 |  | Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C14662 | P14662 |  | Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C14670 | P14670 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C14692 | P14692 |  | Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C14697 | P14697 |  | Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Authority Required procedures - Streamlined Authority Code 14697 |
|  | C14720 | P14720 |  | Ankylosing spondylitis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2023; AND Patient must have had at least 2 of the following prior to commencing non-PBS-subsidised treatment: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months prior to commencing non-PBS-subsidised treatment; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response to NSAIDs and must have been demonstrated prior to initiation of non-PBS subsidised treatment with this biological medicine for this condition: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must have been determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. If the above requirement to demonstrate an elevated ESR or CRP could not be met, the application must state the reason this criterion could not be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |

1. **Schedule 4, Part 1, entry for Upadacitinib**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C11976”:* **P11976**
3. *omit:*

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|  | C12090 | P12090 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C12091 | P12091 |  | Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a BASDAI score. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C12142 | P12142 |  | Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 4 weeks old at the time of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |

1. *insert after entry for Circumstances Code “C11978”:*

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|  | C12174 | P12174 |  | Ankylosing spondylitis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |

1. *omit:*

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|  | C12184 | P12184 |  | Ankylosing spondylitis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |
|  | C12246 | P12246 |  | Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 4 weeks old at the time of application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |

1. *insert in the column headed “Purposes Code” for the Circumstances Code “C13990”:* **P13990**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C13999”:* **P13999**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C14014”:* **P14014**
4. *insert in numerical order after existing text:*

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|  | C14653 | P14653 |  | Severe Crohn disease Balance of supply for Initial (induction) treatment phases Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. The treatment must have been prescribed in a quantity in the most recent prescription which did not seek the full quantity available in regards to any of: (i) the quantity per dispensing, (ii) repeat prescriptions; AND The treatment must provide no more than the balance available under the treatment phase from which the immediately preceding supply was obtained under. | Compliance with Authority Required procedures |
|  | C14655 | P14655 |  | Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C14662 | P14662 |  | Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C14670 | P14670 |  | Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
|  | C14692 | P14692 |  | Ankylosing spondylitis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
|  | C14696 | P14696 |  | Severe Crohn disease Transitioning from non-PBS to PBS-subsidised supply - 'grandfather' arrangements Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 December 2023; AND Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following: (a) patient must have evidence of intestinal inflammation; (b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient. Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. All assessments, pathology tests and diagnostic imaging studies were to have been within 4 weeks leading up to commencing the non-PBS subsidised supply of this drug and should have been performed preferably whilst still on conventional treatment, but no longer than 4 weeks following the last dose of conventional treatment. Where extensive small intestinal disease affecting more than 50 cm of the small intestine applies, the CDAI must have been at least 220 prior to commencing the non-PBS subsidised supply of this drug. If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. | Compliance with Written Authority Required procedures |
|  | C14698 | P14698 |  | Severe Crohn disease Balance of supply for the Continuing (maintenance) treatment phase Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. The treatment must have been prescribed in a quantity in the most recent prescription which did not seek the full quantity available in regards to any of: (i) the quantity per dispensing, (ii) repeat prescriptions; AND The treatment must provide no more than the balance available under the treatment phase from which the immediately preceding supply was obtained under. | Compliance with Authority Required procedures |
|  | C14709 | P14709 |  | Severe Crohn disease Continuing (maintenance) treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). In relation to the immediately preceding supply of this biological medicine, provide at least one of the following which is not more than 4 weeks from the last administered dose: (i) the Crohn Disease Activity Index (CDAI) score, including the date the score was calculated on; or (ii) the unique serial/identifying number and date(s) of pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant. | Compliance with Written Authority Required procedures |
|  | C14710 | P14710 |  | Severe Crohn disease Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND Patient must have evidence of intestinal inflammation; OR Patient must be assessed clinically as being in a high faecal output state; OR Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Provide at least one of the following: (i) the current Crohn Disease Activity Index (CDAI) score, including the date this score was calculated on; (ii) confirmation that there is a documented history of intestinal inflammation plus diagnostic imaging/surgical evidence of at least one of: (a) short gut syndrome, (b) ileostomy, (c) colostomy; (iii) confirmation that there is a documented history and radiological evidence of intestinal inflammation from extensive small intestinal disease affecting more than 50 cm of the small intestine where the CDAI score is at least 220, but below 300. Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. | Compliance with Written Authority Required procedures |
|  | C14711 | P14711 |  | Severe Crohn disease Extended induction period (optional) from weeks 12 to 24 Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have experienced an inadequate therapeutic benefit following at least one of: (i) dosing with 45 mg daily in the initial 12-week induction period, (ii) dosing with 15 mg daily. Patient must be at least 18 years of age. | Compliance with Authority Required procedures |
|  | C14721 | P14721 |  | Severe Crohn disease Initial 1 (induction treatment covering the first 12 weeks in a patient untreated with biological medicine) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must be at least 18 years of age. Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following: (a) patient must have evidence of intestinal inflammation; (b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient. Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. | Compliance with Written Authority Required procedures |
|  | C14728 | P14728 |  | Severe Crohn disease Continuing (maintenance) treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; OR The condition must have not met the improvements specified above due to the prescribed dose being too low - this authority application seeks higher dosing. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). In relation to the immediately preceding supply of this biological medicine, provide at least one of the following which is not more than 4 weeks from the last administered dose: (i) the Crohn Disease Activity Index (CDAI) score, including the date the score was calculated on; or (ii) the unique serial/identifying number and date(s) of pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant. | Compliance with Written Authority Required procedures |
|  | C14734 | P14734 |  | Severe Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND The treatment must not have on a previous occasion failed to provide the patient with an adequate response during the current treatment cycle. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). In relation to the biological medicine prescribed immediately before this one, provide at least one of the following which is not more than 4 weeks from the last administered dose: (i) the Crohn Disease Activity Index (CDAI) score, including the date the score was calculated on; or (ii) the unique serial/identifying number and date(s) of pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; or (iii) confirmation that a severe intolerance occurred that resulted in the cessation of treatment. | Compliance with Written Authority Required procedures |

1. **Schedule 4, Part 1, entry for Zoledronic acid**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C5605”:* **P5605**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C5703”:* **P5703**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C5704”:* **P5704**
5. *insert in the column headed “Purposes Code” for the Circumstances Code “C5735”:* **P5735**
6. *insert in the column headed “Purposes Code” for the Circumstances Code “C9268”:* **P9268**
7. *insert in the column headed “Purposes Code” for the Circumstances Code “C9304”:* **P9304**
8. *insert in the column headed “Purposes Code” for the Circumstances Code “C9317”:* **P9317**
9. *insert in the column headed “Purposes Code” for the Circumstances Code “C9328”:* **P9328**
10. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14729 | P14729 |  | Adjuvant management of breast cancer Patient must be post-menopausal. Patient must not be undergoing PBS-subsidised treatment with this drug for this indication for more than 36 months. | Compliance with Authority Required procedures - Streamlined Authority Code 14729 |
|  | C14735 | P14735 |  | Adjuvant management of breast cancer Patient must be post-menopausal. Patient must not be undergoing PBS-subsidised treatment with this drug for this indication for more than 36 months. | Compliance with Authority Required procedures - Streamlined Authority Code 14735 |

1. **Schedule 5, after entry for Adalimumab**

*insert:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Adefovir | GRP-28116 | Tablet containing adefovir dipivoxil 10 mg | Oral | APO-Adefovir |
|  |  | Tablet containing adefovir dipivoxil 10 mg (S19A) | Oral | Adefovir Dipivoxil Tablets 10 mg (SigmaPharm Laboratories) |

1. **Schedule 5, omit entry for Amoxicillin**
2. **Schedule 5, entry for Amoxicillin with clavulanic acid in the form Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *[GRP-26768]***

*insert in alphabetical order in the column headed “Brand”:* **Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125**

1. **Schedule 5, entry for Clopidogrel in the form Tablet 75 mg (as hydrogen sulfate)**

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

1. **Schedule 5, entry for Filgrastim** **in the form Injection 300 micrograms in 0.5 mL single-use pre-filled syringe *[GRP-23379]***

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

1. **Schedule 5, entry for Filgrastim Injection** **in the form** **Injection 480 micrograms in 0.5 mL single-use pre-filled syringe *[GRP-23385]***

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

1. **Schedule 5, entry for Imatinib in the form Capsule 100 mg (as mesilate) *[GRP-21074]***

*omit from the column headed “Brand”:* **CIPLA IMATINIB ADULT**

1. **Schedule 5, entry for Imatinib**

*omit:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | GRP-25645 | Capsule 100 mg (as mesilate) | Oral | IMATINIB-DRLA Imatinib-APOTEX |
|  |  | Tablet 100 mg (as mesilate) | Oral | Gilmat Glivec IMATINIB RBX Imatinib-Teva |

1. **Schedule 5, entry for Imatinib in the form Capsule 400 mg (as mesilate) *[GRP-21079]***

*omit from the column headed “Brand”:* **CIPLA IMATINIB ADULT**

1. **Schedule 5, entry for Imatinib**

*omit:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | GRP-25647 | Capsule 400 mg (as mesilate) | Oral | Imatinib-APOTEX IMATINIB-DRLA Imatinib GH |
|  |  | Tablet 400 mg (as mesilate) | Oral | Gilmat Glivec IMATINIB RBX Imatinib-Teva |

1. **Schedule 5, entry for Meloxicam in the form Tablet 7.5 mg *[GRP-15658]***

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

1. **Schedule 5, after entry for Morphine in the form Injection containing morphine sulfate pentahydrate 10 mg in 1 mL**

*insert:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | GRP-28109 | Oral solution containing morphine hydrochloride trihydrate 2 mg per mL, 1 mL | Oral | Ordine 2 |
|  |  | Oral solution containing morphine sulfate 2 mg per mL in 100 mL bottle, 1 mL (S19A) | Oral | Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) |
|  |  | Oral solution containing morphine sulfate 2 mg per mL in 500 mL bottle, 1 mL (S19A) | Oral | Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) |
|  |  | Oral solution containing morphine sulfate 10 mg per 5 mL in 100 mL bottle, 1 mL (S19A) | Oral | Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL |
|  |  | Oral solution containing morphine sulfate 10 mg per 5 mL in 300 mL bottle, 1 mL (S19A) | Oral | Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL |

1. **Schedule 5, entry for Olanzapine in the form Tablet 20 mg (orally disintegrating) *[GRP-15643]***

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

1. **Schedule 5, entry for Olanzapine in the form Wafer 20 mg *[GRP-15643]***

*omit from the column headed “Brand”:* **Zypine ODT**

1. **Schedule 5, entry for Olanzapine in the form Tablet 10 mg (orally disintegrating) *[GRP-15723]***

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

1. **Schedule 5, entry for Olanzapine in the form Wafer 10 mg *[GRP-15723]***

*omit from the column headed “Brand”:* **Zypine ODT**

1. **Schedule 5, entry for Olanzapine in the form Tablet 5 mg (orally disintegrating) *[GRP-15797]***

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

1. **Schedule 5, entry for Olanzapine in the form Wafer 5 mg *[GRP-15797]***

*omit from the column headed “Brand”:* **Zypine ODT**

1. **Schedule 5, entry for Olanzapine in the form Tablet 15 mg (orally disintegrating) *[GRP-15953]***

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

1. **Schedule 5, entry for Olanzapine in the form Wafer 15 mg *[GRP-15953]***

*omit from the column headed “Brand”:* **Zypine ODT**

1. **Schedule 5, entry for Ondansetron**

*omit:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | GRP-17042 | Tablet (orally disintegrating) 8 mg | Oral | APO-Ondansetron ODT APX-Ondansetron ODT Ondansetron AN ODT Ondansetron Mylan ODT Ondansetron ODT-DRLA Ondansetron SZ ODT Zotren ODT |
|  |  | Wafer 8 mg | Oral | Zofran Zydis |

1. **Schedule 5, omit entry for Pancrelipase**
2. **Schedule 5, omit entry for Pyridostigmine**